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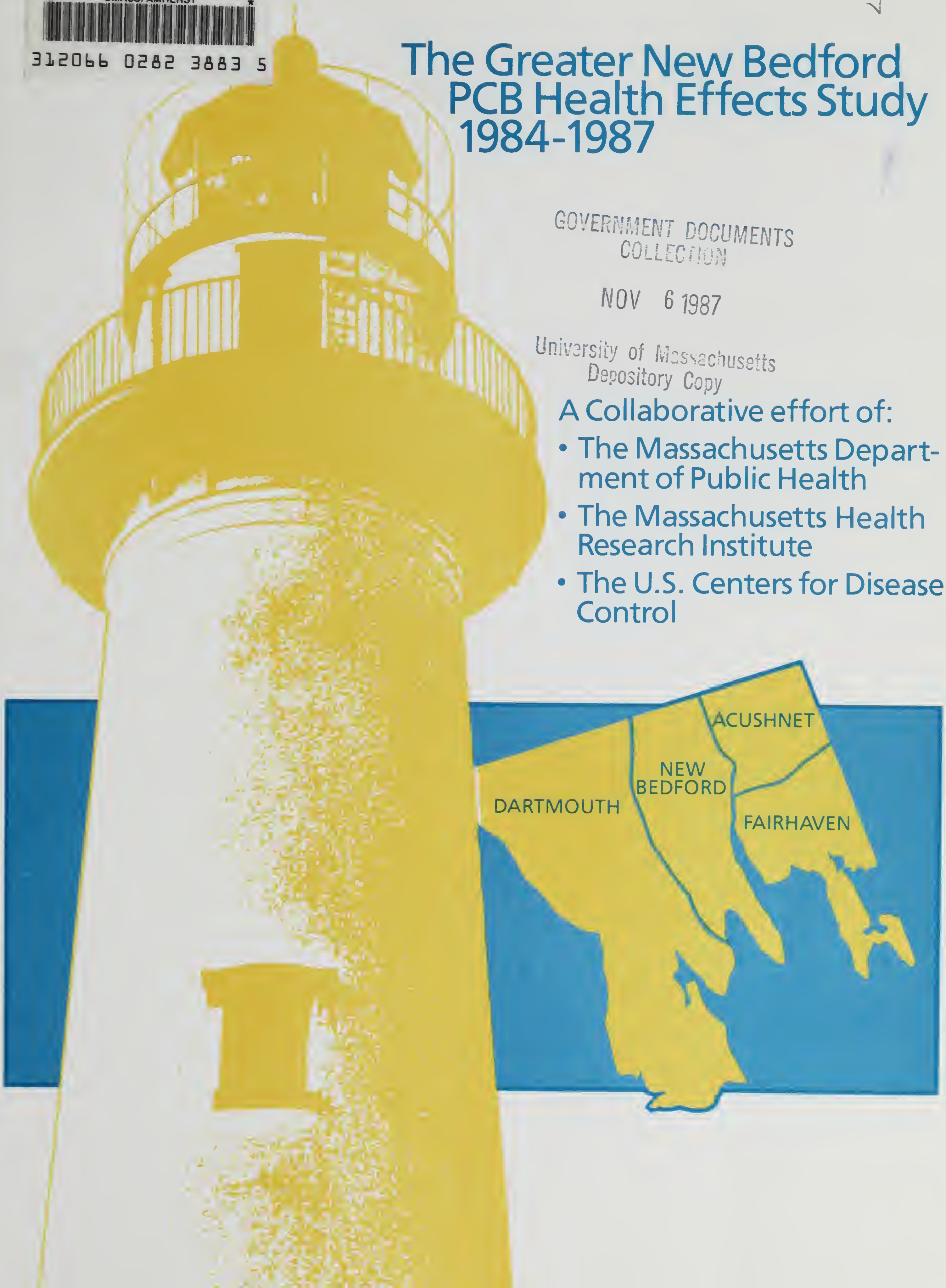

FINAL REPORT

OF

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

1984 - 1987

JUNE, 1987

BOSTON, MASSACHUSETTS

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
150 TREMONT STREET
BOSTON, MASSACHUSETTS

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Additional information on this project may be obtained by writing:

Greater New Bedford Health Effects Study
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ABSTRACT

The Greater New Bedford PCB Health Effects Study (GNBHES) design consisted of two phases: Phase I was designed to determine the prevalence of elevated serum polychlorinated biphenyls (PCBs) levels (≥30 parts per billion {ppb}) among residents of the Greater New Bedford population and to test the hypothesis that serum PCB level is associated with elevated blood pressure measurements. Phase I also sought to identify 150 exposed (≥30 ppb) persons who would participate in a Phase II study to determine the relationship between serum PCB level and a variety of health outcomes.

In 1976, PCBs were found in high concentrations in the Acushnet River estuary adjacent to New Bedford and Fairhaven. Numerous environmental investigations identified PCB contamination of harbor sediment and overlying waters, seafoods harvested from the New Bedford Harbor, and municipal sludge and wastewater. This evidence of widespread environmental contamination extended the concern of human exposure to PCBs from persons occupationally exposed in local electrical manufacturing plants to include persons in the general population who consumed fish from contaminated areas.

Phase I of the GNBHES called for random selection of 1784 residents of New Bedford, Acushnet, Dartmouth, and Fairhaven between the ages of 18 and 64 years. Of the 1482 residents considered eligible for inclusion in the study, 840 individuals chose to participate, a response rate of 57% (Prevalence Study) and were analyzed for individual serum PCB levels. Eleven of the 840 or 1.3% were identified with elevated PCB levels (≥ 30 ppb). Blood pressure levels did not appear to be correlated with serum PCB

levels in the prevalence study group. To identify 150 persons with elevated serum PCB levels (justification for proceeding to Phase II), a contingency plan was implemented to recruit non-randomly selected participants (Enrichment Study) who were at high risk for exposures to PCBs. Seven of these 110 participants or 6.4% in the Enrichment Study had levels $\geq$ 30 ppb.

Specimens of urine and blood were collected from participants in both the prevalence and enrichment studies for analysis of blood lead, urinary arsenic, and urinary mercury. A 10% subset of these specimens was tested for these heavy metals. No evidence was found of excessive exposure to toxic forms of any of the elements tested.

Eligible individuals who refused to participate in the prevalence study appeared to be similar to participants with regard to sex, town of residence, employment history or seafood consumption.

The low prevalence of elevated serum PCB levels that was found in the randomly selected group indicates that significant exposure to PCBs is not occurring in the Greater New Bedford population. However, individuals who eat locally caught seafood from inner New Bedford Harbor tend to have higher concentrations of serum PCBs. Continuation of the study to Phase II with a major health effects phase is not recommended because of the small number of persons found with elevated serum PCB levels.

ACKNOWLEDGMENTS

The Massachusetts Department of Public Health (MDPH), the Massachusetts Health Research Institute (MHRI) and the United States Centers for Disease Control (CDC) gratefully acknowledge the contributions of the staff of the Greater New Bedford PCB Health Effects Study. It was through their hard work and sincere dedication to the community and to the field of environmental health that this difficult epidemiological investigation was completed. The staff included over 20 individuals during a 3 year investigation period; the names and disciplines represented by these individuals as well as the contributions of those acknowledged below are included in Appendix A.

We would like to acknowledge several other agencies and individuals for their assistance with this investigation. They include: the offices of U.S. Senator Edward M. Kennedy (D - Mass.); U.S. Congressman Gerry Studds (D - Mass.); Massachusetts State Senator William Q. MacLean (D - New Bedford); former Massachusetts State Representative Roger Goyette; the MDPH Division of Data Processing; the MDPH Registry of Vital Records, statistics unit; the local media; the New Bedford Immigrant's Assistance Center; the city/town governments of New Bedford, Dartmouth, Fairhaven and Acushnet; the Massachusetts Division of Marine Fisheries (DMF); the office of MDPH Assistant Commissioner Gerald Parker; the MDPH Central Library; the staff of the MDPH Center for Environmental Education and Information; Mrs. Pearl Russo of the MDPH Office of Public Information; Mr. John Figler, CEH/CDC former liaison to the U.S. EPA Region I. Most important, the support and cooperation of the residents of Acushnet, Dartmouth, Fairhaven and New Bedford in this important public health investigation are greatly appreciated.

TABLE OF CONTENTS

Funding Statement..i
Abstract ii
Acknowledgements iv
List of Tables..vii
List of Figures..viii
List of Appendices...ix

I. INTRODUCTION 1

Historical Overview 1
Introduction to the Greater New Bedford Health Effects Study 8

II. METHODS 11

Setting 11
Sample 12
Measurements 18
Questionnaire Development 18
Enrichment Screening Questionnaire Development 19
Refusal Questionnaire Development 20
Quality Control 21
Blood Pressure Measurement Protocol 22
Physical Measurements 23
Laboratory Measurements 23
  Analysis of PCBs in Human Serum 27
  Experience of the MDPH Laboratory in the Analysis of PCBs ... 28
  Sample Handling Procedures 29
  Equipment and Reagents 30
  Extraction and Clean-up of PCBs from Human Serum 31
  Gas Chromatography/Electron Capture Analysis of Serum Extracts ... 32
  Quality Assurance of the Laboratory Analysis for the GNBHES . 33
  Serum PCB Levels Calculated as Parts Per Billion Aroclor 1242 ... 35
  Sample Collection Methods... 35
Data Analysis 38
Limitations 40
Human Subjects Protection 41

III.RESULTS 43

PREVALENCE
Participation Rates 43
Characteristics of the Participant Sample 44
Serum PCB Level... 48
  Level by Reported Ethnicity 48
  Level by Age 53
  Level by Age, Sex, and Residence 53
Seafood Consumption 53
  Seafood Source 56
  Trends in Seafood Consumption 59
  Preferred Species 59
  Serum Levels of PCB and Seafood Consumption 62
    A. Quartile Analysis by Type of Consumption 62
    B. Comparison of Local & General Seafood Consumption 68

Industrial and Occupational Exposure. 71
  Industry of Employment 71
  Selected Manufacturing Exposures 73
  Exposure to Specific Materials 73
Blood Pressure 73
Refusers 77

ENRICHMENT 79
  Level Distribution 79
  Enrichment Level by Ethnicity.... 79
  Enrichment Level by Age.... 79
  Level Range - Prevalence vs. Enrichment 83
Seafood Consumption.... 83
  Seafood Source.... 85
  Trends in Seafood Consumption.... 85
  Preferred Species.... 86
  Enrichment Serum Levels of PCB and Seafood Consumption.... 87
    A. Patterns by Quartile.... 87
    B. Frequency of Local and General Seafood.... 89
Industrial and Occupational Exposure.... 89
  Industry of Employment.... 89
  Selected Manufacturing Exposures.... 91
  Exposure to Specific Materials.... 91
Blood Pressure.... 93

HEAVY METALS IN THE GREATER NEW BEDFORD POPULATION.... 95

IV. DISCUSSION.... 98

V. CONCLUSIONS.... 106

VI. RECOMMENDATIONS.... 109

VII. REFERENCES.... 110

VIII. BIBLIOGRAPHY.... 113

LIST OF TABLES

Table 1. Serum PCB Results for 322 Greater New Bedford Residents......10
Table 2. Participation Rate by Age, Sex and Residence for Prevalence Sample..45
Table 3. Total Expected and Observed Participation by City/Town.......46
Table 4. Expected and Observed Participation by Age, Sex and Residence...47
Table 5. Distribution of Serum PCB Levels--Prevalence.................49
Table 6. Distribution of Serum PCB Levels by Ethnicity-Males..........51
Table 7. Distribution of Serum PCB Levels by Ethnicity-Females........52
Table 8. Serum PCB Levels by Residence, Age and Sex. Mean and Standard Deviation, Range and Median. Prevalence.........55
Table 9. Present Source of General Seafood............................57
Table 10. Past Source of General Seafood..............................57
Table 11. Present Source of Local Seafood.............................58
Table 12. Past Source of Local Seafood................................58
Table 13. Trends in Consumption Among Consumers of Seafood............60
Table 14. Percent Consuming Various Species...........................61
Table 15. Questions on Local Seafood by Quartile-Prevalence-Males......63
Table 16. Questions on Local Seafood by Quartile-Prevalence-Females....65
Table 17. Industry of Employment by Quartile - Prevalence..............72
Table 18. Selected Manufacturing Exposure by Quartile - Prevalence.....74
Table 19. Material Exposure by Quartile - Prevalence...................75
Table 20. Distribution of Serum PCB Levels - Enrichment................80
Table 21. Serum PCB Level Distribution Among Portuguese and Cape Verdean as Compared to All Others - Enrichment.........81
Table 22. Local Fish Consumption Patterns by Quartile - Enrichment.....88
Table 23. Industry of Employment by Quartile - Enrichment..............90
Table 24. Selected Manufacturing Exposure by Quartile - Enrichment.....92
Table 25. Materials Exposure by Quartile - Enrichment..................94

LIST OF FIGURES

Figure 1 Structural Formula for PCB....................................2
Figure 2 Map of Closure Areas..4
Figure 3 PCBs in Soil - Norwood..6
Figure 4 Final Disposition of the Random Selection Process.............17
Figure 5 Serum Handling, Processing, and Analysis at CL/MDPH...........24
Figure 6 Urine Collection..25
Figure 7 Blood and Serum Collection....................................26
Figure 8 Serum PCB Level Distribution of Prevalence Sample.............50
Figure 9 Mean and Standard Deviation Serum PCB Level by Age Group......54
Figure 10 Comparison of Local and General Seafood Consumption for the Prevalence Sample..69
Figure 11 Comparison of Serum PCB Level with frequency of Local Seafood Consumption..70
Figure 12 Mean Serum Level and Standard Deviation by Age Group for Enrichment...82
Figure 13 Serum PCB Level Comparison of Enrichment with Prevalence Control Group..84

LIST OF APPENDICES

A. Greater New Bedford Health Effects Study Staff
B. Letter to Selected Respondents
C. Letter to Area Physicians
D. Letter to Area Employers
E. Certified Letter
F. Letter to Enrichment Sample
G. Enrichment Screening Questionnaire
H. Refusal Questionnaire
I. Mail-Out Refusal Questionnaire
J. Cover Sheet/Call Record
K. Consent Form
L. Interview (English and Portuguese)
M. Urine Specimen Sheet
N. Phlebotomy Sheet
O. Residential Supplement
P. Capacitor Supplement
Q. Electrical Equipment/Waste Treatment Supplement
R. Material/Product Exposure Supplement
S. Home Visit Kit Supply List
T. Participant Blood Pressure Instruction Sheet
U. Interviewers Manual
V. Specimen Collection and Shipping Protocol
W. Sample Size Power Estimates
X. Cooperative Agreement
Y. Summary of Proposal
Z. Sampling Plan
AA. Blood Pressure, Skinfold, Height and Weight Measurement Protocol
BB. Heavy Metal Analyses
CC. Human-Subject Review Committee Approval
DD. Analysis Protocol for PCBs and Other Chlorinated Compounds of Environmental Concern: CDC-New Bedford Study
EE. Chromatograms
FF. Listing of Reasons for Refusal
GG. Prevalence of Chlorinated Pesticides in the Serum of a Subset of the New Bedford Cohort
HH. 1242 Serum PCB Levels
II. Correlation
JJ. Data Analysis
KK. Laboratory Quality Control
LL. Report and Membership of the Peer Review Committee

CHAPTER I

INTRODUCTION

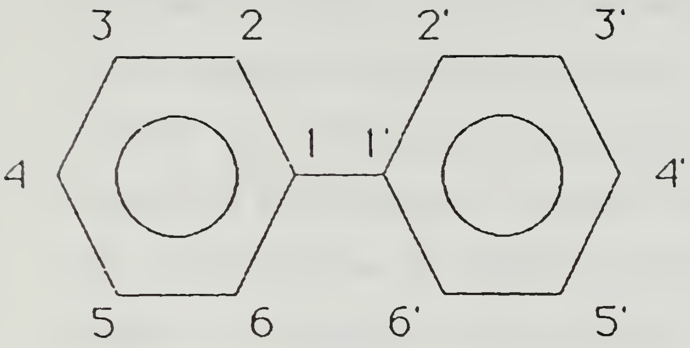
HISTORICAL OVERVIEW

Polychlorinated biphenyls (PCBs) refer to a class of chemical compounds with 209 possible congeners in which chlorine atoms have replaced some or all of the hydrogen atoms in the biphenyl molecule (Figure 1). The number and location of the chlorine atoms are responsible for the PCBs' chemical properties and toxicity. In general, the higher the chlorine content of the compound, the more persistent it is. PCBs are generally odorless and colorless, have excellent thermal and chemical stability, are fire resistant, non-conductive and virtually insoluble in water. (1) These properties made PCBs ideal for a variety of industrial applications.

During the years of PCB use in Greater New Bedford, the Acushnet River estuary and New Bedford Harbor became contaminated with PCBs through the discharge of contaminated waste water and improper disposal of defective capacitors. In New Bedford, PCB use began in the early 1940s. PCBs were used primarily as a liquid coolant in the manufacture of electrical transformers and capacitors. Other possible industrial uses for PCBs were lubricants, machine tool cutting oils, and immersion oil for microscopes. In addition, they were added to a variety of other products including paints, adhesives, sealants, varnishes, dedusting agents, pesticides, herbicides, and carbonless copy paper (2,3,4). The U.S. Environmental Protection Agency (EPA) officially banned the manufacture of PCBs and their use in open systems in 1979 (44 FR 31515).

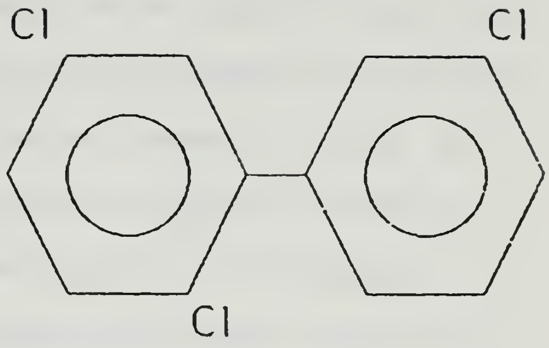
PCBs entered the aquatic food chain by binding with sediments and

FIGURE 1



STRUCTURAL FORMULA OF

THE BIPHENYL MOLECULE



STRUCTURAL FORMULA OF

3,3',6-TRICHLOROBIPHENYL

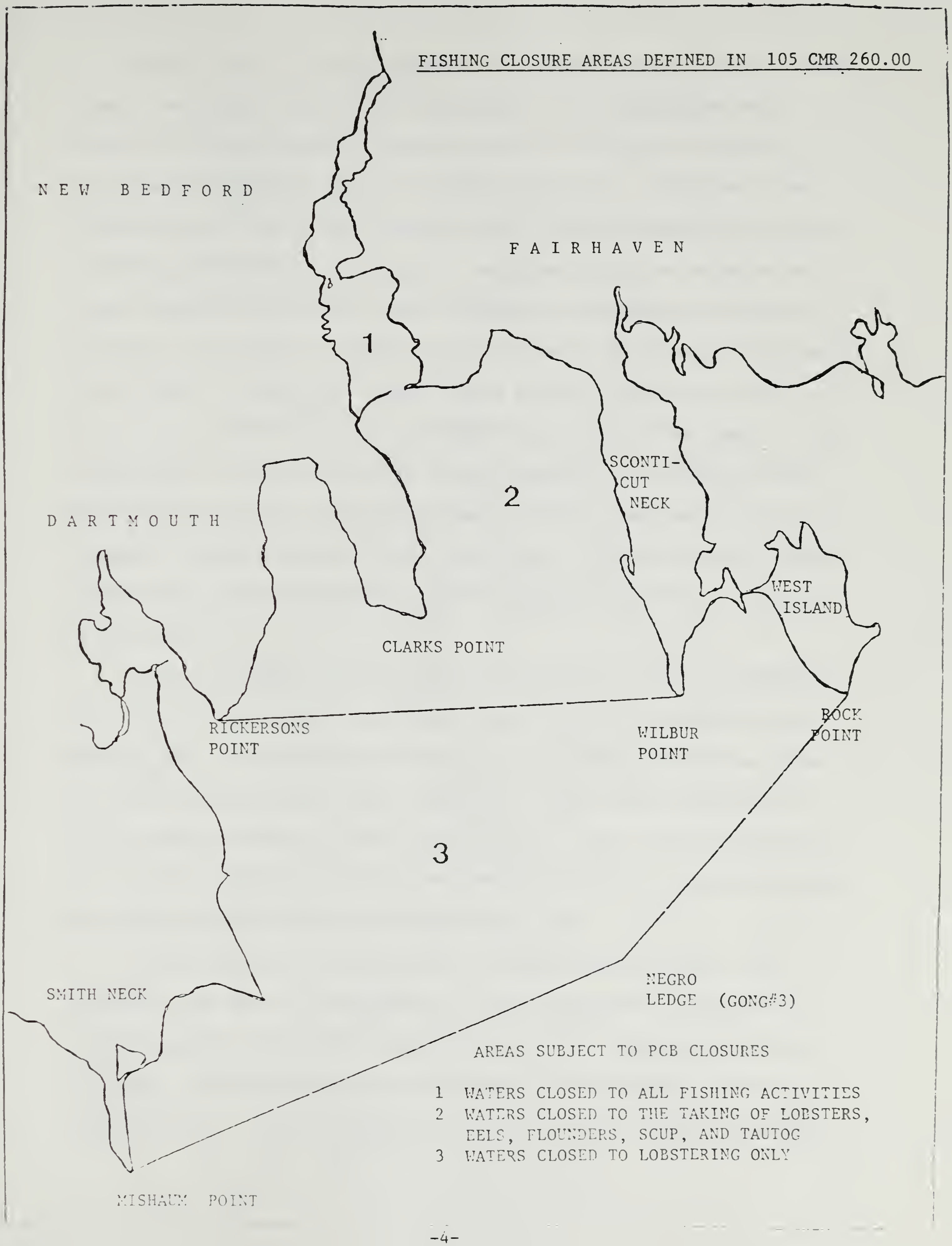
The biphenyl molecule has ten positions that are available for chlorine atoms (the positions labeled 2-6 and 2'-6'). There are 209 possible compounds (PCB congeners) that can be formed by different levels of chlorination. For example, there are 24 possible trichlorobiphenyls (PCBs with 3 chlorine atoms), but only one decachlorobiphenyl (10 chlorine atoms).

particles eaten by lower forms of aquatic life. The PCBs were then passed up through the food chain via predator/prey relationships (2) resulting in the contamination of higher forms of marine life such as fish and lobster. The levels of PCBs in fish in New Bedford were greater than the 5 parts per million (ppm) tolerance set by the U.S. Food and Drug Administration (FDA) in 1973. (5) More recently, the FDA tolerance was lowered to 2 ppm. (6) Since PCBs bioaccumulate, the most logical route of exposure to PCBs for the 140,000 Greater New Bedford residents was ingestion of contaminated seafood. In response to these findings, the MDPH promulgated regulations to close the contaminated area to commercial fishing in September of 1979. (7)

The closure area (Figure 2) was divided into three sections. The most contaminated area, identified as Area 1, included waters north of the hurricane dike in New Bedford Harbor and was closed to all fishing. Area 2, south of Area 1, extended out to Ricketson's Point in South Dartmouth and westerly across to Wilbur Point on Sconticut Neck in Fairhaven. Area 2 was closed to lobstering and to the taking of bottom-feeding fish including flounder, eels, scup and tautog. Area 3, south of Area 2, was closed only to lobstering and extended out to Mishaum Point in South Dartmouth, westerly across to gong #3 on Hursett Rock and continued northwest to Rock Point on West Island in Fairhaven. The entire closure area encompasses approximately 28 square miles.

Although regulatory intervention has prevented commercial fishermen from obtaining seafood in the contaminated area, recreational fishing still occurs because of difficulties in enforcing these types of activities. As a result, the EPA and the Massachusetts Department of Environmental Quality Engineering (DEQE) installed numerous bilingual warning signs around the closure area.

FIGURE 2



FISHING CLOSURE AREAS DEFINED IN 105 CMR 260.00

AREAS SUBJECT TO PCB CLOSURES

1 WATERS CLOSED TO ALL FISHING ACTIVITIES
2 WATERS CLOSED TO THE TAKING OF LOBSTERS, EELS, FLOUNDERS, SCUP, AND TAUTOG
3 WATERS CLOSED TO LOBSTERING ONLY

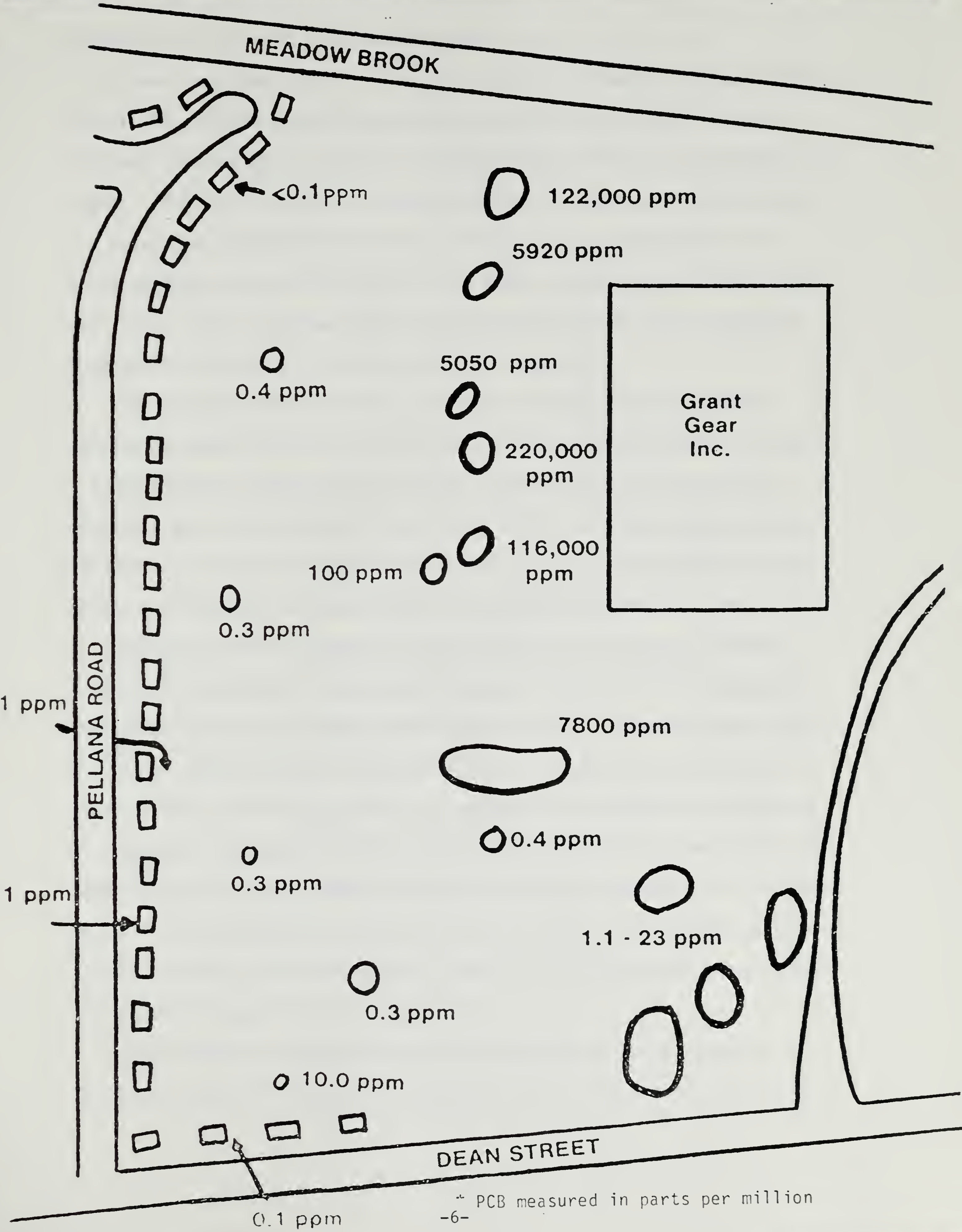
Another source of non-occupational PCB exposure among residents of the Greater New Bedford area was via skin contact with contaminated soil present in the environment. There are several sites (e.g., landfills, river banks) throughout the area in which high levels of PCBs have been discovered in the soil. (8) Analyses of soil samples revealed high levels in Greater New Bedford. This route of exposure to PCBs was examined in a study conducted by the MDPH in 1984 in Norwood, Massachusetts (Figure 3), and also in other sites in the U.S. investigated by the Centers for Disease Control (CDC). Some of the highest levels of PCBs discovered in soil in the U.S. were observed in Norwood (220,000 parts per million {ppm}). This investigation involved collection of human serum to be analyzed for PCB. MDPH selected a group of 90 people thought to be at the greatest risk of exposure. The mean serum PCB level was 4.9 ppb. From this study it would appear that contact with ambient soils may not be a significant exposure route to PCBs.

In 1981 and 1982, two pilot studies of serum PCB levels of volunteers who reported eating local seafood were conducted by CDC and MDPH in New Bedford. (9) In the first study, nine of the 21 (43%) subjects had serum PCB levels greater than or equal to 30 ppb. In the second study, 31% of the 51 subjects tested at levels greater than or equal to 30 ppb. At that time, the CDC estimated that only one percent of the U.S. population would be likely to have levels greater than 30 ppb. (10)

A recent review of the laboratory and human studies on PCBs (11) indicated that PCBs are carcinogenic, affect reproduction, supress the immune response, and produce hepatic porphyria when ingested in a variety of species. Once ingested, PCBs are stored in fatty tissues including human milk fat. Evidence suggests that the more chlorinated or more toxic

FIGURE 3

PCBs* IN SOIL - NORWOOD



* PCB measured in parts per million

compounds are excreted from the body quite slowly. (12)

There have been few cross-sectional studies of humans exposed to PCBs. However, no studies demonstrated sufficient statistical power or were followed long enough to support or refute whether PCBs were carcinogenic in humans. One study reported a strong association between serum PCB level and diastolic blood pressure readings; however, this association was weakened when age was controlled (13). Other studies reported that high PCB levels were associated with high serum cholesterol levels, elevated triglyceride levels and induction of liver enzymes.

The studies which contribute the most information about general population serum PCB levels are the ones conducted in Michigan to evaluate a widespread PCB contamination episode. One Michigan study reported a geometric mean serum PCB level of 6.4 ppb (14). In other surveys almost exclusively of volunteer populations, one can expect to see 95% of serum levels falling below 20 ppb and 99% falling below 30 ppb. (15, 19)

Because seafood consumption is now regarded as the most plausible nonoccupational route of exposure, concerted inquiry has been mounted in populations known to consume contaminated fish. The largest study to date was in the town of Triana, Alabama in 1979. This was a cross-sectional study of 600 rural black residents to determine the possible consequences of consuming fish contaminated by DDT, the result of the presence of a DDT manufacturing facility. Mean fish consumption was documented at 4.3 fish meals per month before the publicizing of the study. During the analysis of blood serums, PCB levels ranging from 3.2 to 158 ppb were noted, with the geometric mean being 17.2 ppb. (13)

Fish consuming populations have also been evaluated in Michigan. These populations are generally composed of sports fishermen or volunteers.

In 1973, Humphrey (16) looked at a small population of heavy fish eaters from the Lake Michigan area and documented a 4-fold increase in PCB levels as compared to non-fish eaters. A larger study of 572 Michigan sports fishermen (17) showed a lower mean PCB level of 21.7 ppb, but again higher concentrations for heavy (i.e. more frequent) versus light fish eaters.

In the Triana study, serum cholesterol was positively associated with serum PCB levels. Independent of other major predictors of PCB level such as age, sex, fish consumption, body mass index and alcohol consumption. Triana results introduced the hypothesis that PCBs may be related to elevated blood pressure. Kreiss et al found diastolic blood pressure measurements and serum PCB levels were significantly related. A major weakness of the study was the collinearity between DDT and PCB levels in the Triana population. An analysis performed with patients from the Yusho (PCB poisoning) incident did not show a relationship between blood pressure and PCB levels (18). Therefore, this relationship is open to question.

The literature demonstrates further work is necessary in two areas: 1) greater attention must be paid to the PCB-elevated blood pressure hypothesis, and 2) larger non-volunteer populations must be examined for the prevalence of PCB exposure while both occupational and non-occupational exposures are examined simultaneously.

Introduction to the Greater New Bedford Health Effects Study

As a result of the widespread environmental contamination (i.e., heavy metals, PCBs, etc.) and of the preliminary findings of the 1981 and 1982 pilot studies (9), a proposal for a two-phase epidemiological investigation was developed by the MDPH in cooperation with the CDC. The first phase was designed to determine the prevalence of elevated serum PCB levels in the

Greater New Bedford population (i.e., residents of Acushnet, Dartmouth, Fairhaven and New Bedford), and to determine whether there was a relationship between serum PCB levels and systolic/diastolic blood pressure levels. The second phase was designed to compare two groups of 150 individuals each and examine possible health effects associated with PCB exposure. On the basis of studies conducted in other communities that included presumably unexposed cohorts, CDC estimates that 99% of unexposed persons in the United States have PCB levels less than 30 ppb and 95% have levels below 20 ppb (19). An exposed group, that is, individuals with serum PCB levels greater than 30 ppb, would be compared in the second phase of the study to an unexposed group of individuals with serum PCB levels less than 10 ppb for a variety of clinical and laboratory measurements.

After a review of the first 322 serum specimens (Table 1), it was determined that the first phase data would not identify a sufficient number of exposed individuals to study in the second phase. Only 4 (1.2%) of the entire group of 322 individuals had serum PCB levels $\geq$ 30 ppb. Preliminary data analyses suggested that those residents with serum PCB levels greater than or equal to 15 ppb had consumed a great deal of contaminated seafood caught in and around the closure area. This observed difference remained constant even after confounding variables were removed.

On the basis of these findings, the MDPH and the CDC decided to conduct an Enrichment Study. The Enrichment Study consisted of Greater New Bedford residents suspected to be at high risk for PCB exposure because of ingestion of moderate to high amounts of seafood from the contaminated areas and an occupationally exposed group obtained from the list of 1981 pilot participants. The goal of recruiting these individuals was to provide 150 exposed residents necessary for conducting Phase II.

Table 1.

Serum PCB Results for 322
Greater New Bedford Residents

PCB level	Aroclor 1254	
	n	%
30 + ppb	4	1.2
20 - 29.99 ppb	4	1.2
10 - 19.99 ppb	28	8.7
0 - 9.99 ppb	286	88.8

n = number of respondents

% = percent of results on 322 respondents

ppb = parts per billion

CHAPTER II

METHODS

The objectives of the Greater New Bedford PCB Health Effects Study were to:

1) determine the prevalence of PCB exposure among residents of Greater New Bedford, and

2) to determine whether or not a relationship exists between serum PCB levels and levels of systolic and diastolic blood pressure.

Phase I also sought to identify 150 exposed ($\geq$30 ppb) persons who would participate in a Phase II study. These objectives were met by obtaining a cross-sectional, random sample (stratified by age and sex) of 840 residents of Acushnet, Dartmouth, Fairhaven and New Bedford. This chapter focuses on the methodological design of the Greater New Bedford PCB Health Effects Study.

SETTING

The Greater New Bedford area encompasses four cities and towns (Acushnet, Dartmouth, Fairhaven and New Bedford) within the Southeastern section of the State of Massachusetts. The total population is 140,000; the greatest number of individuals residing in the City of New Bedford. It is culturally diverse with 36% of the residents speaking Portuguese, 6% Spanish and 58% English. New Bedford is approximately 66 miles from Boston, the major metropolitan center in Massachusetts. New Bedford has long been identified as the whaling capital of the world. Herman Melville

may have described New Bedford best when he said, "The town itself is perhaps the dearest place to live in, in all New England. It is a land of oil, true enough: but not like Canaan; a land, also, of corn and wine. The streets do not run with milk; nor in the springtime do they pave them with fresh eggs. Yet, in spite of this, nowhere in all America will you find more patrician-like houses; parks and gardens more opulent, than in New Bedford." (20)

The remaining three towns within the study area are much smaller in terms of both geographic boundaries and total population. Further, the ethnic variation of each of these three towns is somewhat different from that of the City of New Bedford.

SAMPLE

Statisticians at the CDC and statistical consultants using a variety of power calculations concurred that a sample of 840 individuals was adequate to detect a doubling of the prevalence of elevated serum PCB levels to 2% or more at a .05 significance level and a power of .80 (Appendix W). Although the original sampling plan (Appendix Z) placed this estimate much higher, the recalculated sample size was determined to be adequate. The age range of the sample was 18 to 64 years. Children were excluded because it was unlikely that they had elevated serum PCB levels due to limited time exposure. Persons 65 years and older were also excluded from the study because they were more likely to have other pathologies that would confound interpretation of the findings.

After a review of available source lists (e.g., documents listing households, addresses, residents) from which the sample could be drawn, it was determined that the most appropriate and complete sampling vehicles

were the annual census that each city and town in Massachusetts was required to conduct. The census lists are ordered by wards (New Bedford only), and then, by precinct (all other towns). Streets within each precinct are listed alphabetically and individual residents 17 years of age and older are ordered by street number. Census lists for each city/town were updated by study staff to make address changes and additions by using various other city/town records (e.g., voter registration change of address forms).

In order to obtain a representative sample of the four town area, a two level proportional stratification by city/town, and then by sex within each community was performed. Accordingly, each town was sampled in proportion to its contribution to the total male and female 18 to 64 years old population. Based on 1980 Federal Census figures, these proportions were 65.5% from New Bedford, 17.4% from Dartmouth, 10.9% from Fairhaven, and 6.3% from Acushnet.

The MDPH Division of Data Processing generated a list of random numbers for each town, using a modified Statistical Analysis System (SAS) Program for Random Number Generation. Each number represented a page number and a line number in a particular town's census. Accordingly, every person listed on any randomly selected page had an equal probability of selection for the study. An eligible individual was defined as any person 18 to 64 years of age who had lived in the Greater New Bedford area for five years or more since 1940.

In order to compensate for ineligible individuals and an assumed 75% participation rate, 3900 random numbers were generated. These numbers were batched in groups of 133 with each city/town represented proportionally. At the beginning of the study, the census for several wards in New Bedford

had not been updated. Consequently, a number of empty lines for selected random number pages resulted. In order to select the appropriate proportions in the sample, it was necessary to assign more random numbers per batch for New Bedford. Later, during the course of the study, when the update of the census was completed, individuals who would have been sampled earlier were identified and invited to participate in the study.

Community outreach efforts such as press conferences, newspaper, radio and television coverage and distribution of posters, as well as solicitation letters to the local medical and business communities, (Appendices C and D), preceded initial contact with selected respondents and continued throughout the study period.

Selected residents were sent a letter in English and Portuguese signed by the Commissioner of the Massachusetts Department of Public Health as well as by representatives of the four local Boards of Health. The letter served to inform a resident of his/her random selection in the Greater New Bedford Health Effects Study and explained the purpose of the study (Appendix B). Telephone follow-up by study staff determined age and residence eligibility of each candidate. An appointment was scheduled for all eligible individuals who agreed to participate. Postcards confirming each appointment and reminding the subject to fast for 12 hours before the appointment were mailed 1 week before the appointment.

If, at the time of initial telephone contact, an individual was identified who did not speak English, the candidate's cover sheet was distributed to a bilingual interviewer. The same protocol was followed for English, Spanish and Portuguese speaking candidates. Attempts were made from the beginning to offset any logistical reasons for refusal. For instance, when transportation was identified as an obstacle for

participation in the study, cabfare was supplied by the project.

A cover sheet with a call record (Appendix J) was used to record efforts to reach randomly selected individuals. Calls and home visits were recorded with the date and time of the phone call or home visit and the interviewer identification number (a home visit was determined as an actual trip to the address listed for a resident in the city/town census listing). Candidates who initially refused to participate were recorded as "IR", and space was provided to record the reason for refusal and any other pertinent comments. Follow up calls to these individuals continued until there was a final disposition of each case. The disposition of all home visits/phone to possible participants was recorded on individual cover sheets.

Staffing and scheduling were designed to maximize subject participation. There were five staff interviewers. One interviewer was bilingual in English and Portuguese and another interviewer was trilingual in English, Spanish, and Portuguese. The study office was open two evenings a week and every other Saturday. Saturday was the most popular choice of participants, and 23.3% of the interviews took place on that day.

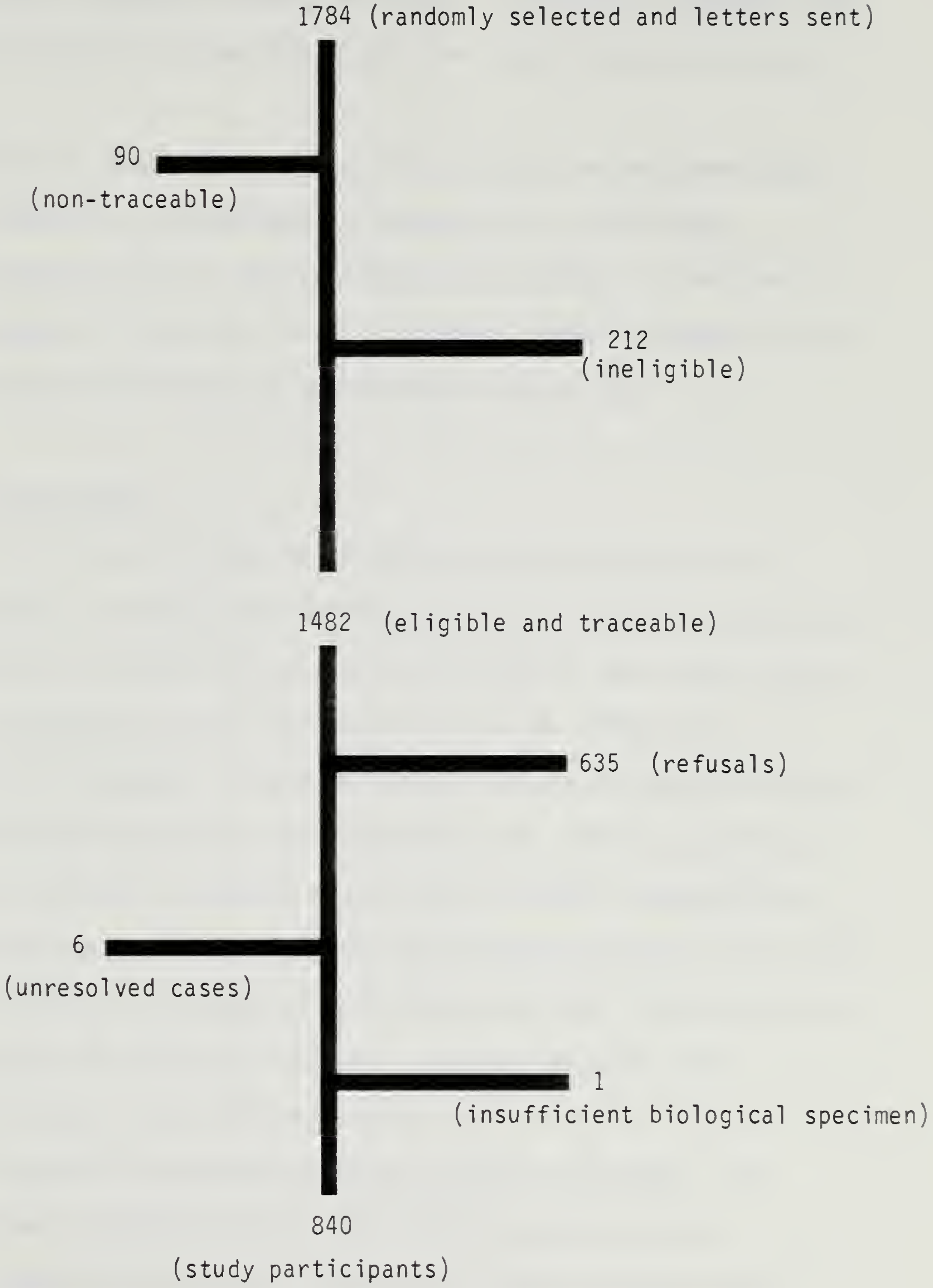
A campaign to follow-up individuals who had initially refused to participate was established in October, 1985. These individuals received a second telephone call and were again asked to participate. If the candidate refused a second time during this call, they were asked to complete the refusal questionnaire (Appendix H and I) and he/she was coded as final refusal. This procedure was also used for home visits to individuals who did not have a telephone or did not have a phone number listed in the local telephone directory.

In order to attain a final disposition for all randomly selected candidates, study staff made a maximum of thirty telephone calls and

four home visits for each individual. If in the course of a home visit no one was home, a letter was left for the person, which explained the purpose of the study and asked him/her to call the study office (Appendix E). Study staff visited homes in a sequence of day, evening, and Saturday visits over a period of time to ensure contact with individuals who were working or were otherwise occupied outside the home. Individuals who proved especially difficult to locate or contact were sent certified letters. Because the home visit and certified letter approaches were costly in terms of staff time and monies, a decision was made in February of 1986 to code an initial refusal resulting from a home visit or a certified letter as a final refusal. There was no further effort made to recontact such individuals. All other initial refusals, with few exceptions, were contacted a second time before their status was finalized. Possible participants whose letters were marked as non-deliverable by the postal service and returned to the study office were classified as non-traceable, after the address had been double checked in the census. Ninety persons fell into this category. Tracking efforts led to no information on the current whereabouts of these individuals. Clear distinctions were drawn between non-traceable individuals and final refusals. These distinctions included evidence that the randomly selected individual did exist other than as a census listing. Family, friends or neighbors were interviewed to verify if an individual was, in fact, refusing to answer our telephone calls or letters. Lack of a response by mail or telephone was not considered a refusal without appropriate staff follow-up. The final disposition for all randomly selected individuals is shown in Figure 4.

FIGURE 4

FINAL DISPOSITION OF THE RANDOM SELECTION PROCESS
FOR
THE GREATER NEW BEDFORD HEALTH EFFECTS STUDY


1784 (randomly selected and letters sent)
90
(non-traceable)
212
(ineligible)
1482 (eligible and traceable)
635 (refusals)
6
(unresolved cases)
1
(insufficient biological specimen)
840
(study participants)

MEASUREMENT

A variety of tests were conducted on participants of the Greater New Bedford PCB Health Effects Study. They included measurements of blood pressure, skinfold thickness, height and weight. Biological specimens were collected for analyses of serum PCB, blood lead, and urinary arsenic and mercury.

In addition to physical and biological testing, subjects were also requested to respond to a questionnaire (Appendix L). Individuals recruited for participation in the Enrichment study were also required to respond to a series of questions in the enrichment screening questionnaire (Appendix G) before being asked to participate in the study.

Questionnaire Development

A draft survey was included in the 1984 project protocol, but it needed improvements in coding instructions, question format and preparation for computerization. Copies of previous questionnaires from local surveys, the CDC, and the National Center for Health Statistics (NCHS) were collected as source documents. Many of the questions were extracted from previous national surveys to provide reliability and content validity as well as comparison data. The major health questions were from the NCHS 1985 Health Interview Survey (medical and occupational sections only) which were adapted from PCB questionnaires developed by the CDC. Other questions on occupation were from the Census Bureau. Seafood questions were developed with project staff and consultants.

A draft survey instrument was developed before pretesting. An Interviewer's Manual (Appendix U) was developed to accompany the questionnaire. Additional materials needed for use during interviewing

were supplied by the Division of Marine Fisheries (DMF), and "prompt" cards were prepared by interviewing staff.

Interviewer training began in the spring of 1985 and continued through the fall of 1985. In addition, regular informational sessions were held to discuss any problems. A final draft was then pretested on 25 randomly selected respondents. This pretest began on April 22, 1985. Final reformatting changes were completed following the pretest, and the actual prevalence data collection began on May 10, 1985. All other methods and procedures including laboratory testing had been rehearsed during the pretest. A Portuguese translation was completed in June, and the trilingual interviewer did her own translations as needed for Spanish participants. A systematic procedure for editing and computer-coding was also developed.

Enrichment Screening Questionnaire Development

Based on preliminary data analyses of the Phase I serum samples, a screening questionnaire gauging potential occupational and environmental exposures was developed to ensure identification of persons more likely to be at risk of exposure to PCBs and, subsequently, have elevated serum PCB levels. Individuals were identified by existing fishing/lobstering license records obtained from local city/town halls and the DMF.

The questionnaire was administered over the telephone to all potential respondents before they were asked to participate in the study. The questionnaire consisted of age, residence years, past or present employment at either of the two electrical manufacturing firms in the Greater New Bedford area and an abbreviated history of fish/shellfish consumption taken from the Phase I interview. This included: 1) types of

fish and shellfish consumed, 2) frequency of consumption, 3) total number of years of consumption, and 4) whether the seafood consumed had been caught locally (i.e., in the closure area).

All the answers to questions on the screening questionnaire were weighted numerically according to their PCB exposure potential. Since local lobsters have been shown to have consistently higher PCB concentrations than, for example, local tautog (21), a person reporting frequent consumption of local lobster received more points than a person reporting frequent consumption of local tautog. Likewise, a person living in the Greater New Bedford area for 50 years received more points than a person in residence only 10 years.

Initially, all candidates who accumulated at least 100 points were considered eligible for the Enrichment Study. This requirement was later amended to include only persons with greater than 125 points who also consumed local seafood.

Refusal Questionnaire Development

To assess the comparability between the refusal population and the study participants, another questionnaire was developed to administer to refusers after all attempts at follow-up were exhausted (Appendices H and I). The questionnaire was designed to solicit a maximum amount of information with a minimum time commitment on the part of the refuser. Information regarding age, sex, residence and occupation were obtained from the individual's cover sheet. Native language was determined by the staff person administering the refusal questionnaire. Information for other important areas of comparison was obtained from the individual refusal either on the telephone, during a home visit or through the mail.

Questions included: 1) previous or present employment at one of the local capacitor manufacturing firms, 2) quantity and source of any seafood consumed, and 3) recurring medical conditions. Reason for refusal was included to provide information on why individuals were refusing to participate.

Quality Control

All interviews except those conducted in a foreign language were tape recorded for quality control. Other exceptions included respondents who agreed to complete the interviews, but refused to have the proceedings tape recorded, and some tapes were not of sufficient mechanical quality. Of the 840 prevalence interviews, 582 (69%) were taped, and for the Enrichment Study, 97% of 110 (88%) interviews were taped.

The standardized quality control plan involved listening to every fifth tape completely. For the Prevalence Study, 252 tapes were listened to completely (30%); for the Enrichment Study, 42 tapes (38.2%) were listened to completely. The primary goal was to insure accuracy, i.e., to eliminate coding errors, to monitor interviewing techniques, etc. Comments were recorded on quality control sheets and used for final editing. The section of the questionnaire that focused on seafood consumption (Questions 23-35) was listened to on every available tape because of its detailed nature.

Editing was designed to ensure accuracy and standardization of coding. In the case of missing information, a decision based on the importance of the question, was made whether or not to call back the respondent. Coding of census tracts was done by using Regional Census Codes; occupational coding was done by using NIOSH occupation codes.

Quality control of the occupational coding was performed by the staff in the statistics unit of Vital Records at MDPH. Coding of medical conditions was done according to the International Classification of Diseases (1975 revision).

A complete set of computer codes was established by October 4, 1985, and edited interviews were sent to the MDPH Division of Data Processing at a rate of 30 to 40 per week. All interviews were verified by staff for any discrepancies between the survey instrument and the computer printout to check for key punching errors. After this verification and editing process, the corrections were resubmitted to Data Processing for entry.

Blood Pressure Measurement Protocol

The Hawksley Random Zero Sphygmomanometer, a mercury manometer manufactured in Britain and designed to eliminate observer bias, was used for this study to minimize observer bias and digit preference. The zero point is varied randomly between 0 and 20mm Hg. The true zero point cannot be determined until after the blood pressure is taken. Then the value is subtracted from the measurement (Appendix AA).

Three blood pressure measurements were recorded for each of the study participants, once each at the beginning, middle and the end of the interview. Each subject was classified with a normal, borderline, or definite high blood pressure. Normal blood pressure was defined as a systolic measurement of less than 140mm Hg and a diastolic measurement of less than 90mm Hg. Borderline high blood pressure was defined as a systolic measurement of 140 to 159mm Hg and a diastolic measurement of 90 to 104mm Hg. Definite high blood pressure was defined as a systolic measurement greater than 160mm Hg and a diastolic measurement greater than

104mm Hg. Individuals with borderline or high blood pressure were referred to a nurse or physician within a month for a repeat measurement and/or treatment. If subjects stated that they did not have a regular source of health care, they were referred to the Greater New Bedford Community Health Center Blood Pressure Clinic. Respondents with a systolic blood pressure of greater than 200mm Hg or a diastolic blood pressure of greater than 115mm Hg were referred to the emergency room at one of the local hospitals.

Physical Measurements

Since PCBs concentrate in fat tissue, it was important to obtain an accurate estimate of skinfold thickness and measurements of height and weight (Appendix AA). These latter measurements were also used to establish body mass index (wt/ht^2) for individual study participants.

Laboratory Measurements

Laboratory analyses were done for serum PCBs, serum chlorinated hydrocarbons, PCB congeners, blood lead, and urinary arsenic and mercury levels (Figures 5, 6, 7). Determinations of serum PCB levels were done in the Environmental Laboratory at the Massachusetts Department of Public Health's Center for Laboratories (MDPH/CL). Serum chlorinated hydrocarbons, PCB congeners, blood lead and urinary arsenic and mercury determinations were done at the Division of Environmental Health Laboratory Sciences, Center for Environmental Health, U.S. Centers for Disease Control (CEH/CDC). As a quality control check, CEH/CDC performed PCB analyses on a subset of serum specimens also analyzed by MDPH/CL for serum PCBs. A 5% subset of specimens was assayed for chlorinated hydrocarbons by CEH/CDC using packed column gas chromatography with electron capture detection.

FIGURE 5

SERUM HANDLING, PROCESSING AND ANALYSIS AT CL/MDPH

4 ml. Serum

Denaturation with Methanol

Extraction with mixed solvents
hexane:ethyl ether (1+1)

Concentration by nitrogen drying

Separation on Silica Gel Column

Concentration by nitrogen drying

Reconstitution with DCB

Detection and Quantitation of Gas
Effluent from GC Chromatography
Column by Electron Capture Detector

FIGURE 6

URINE COLLECTION

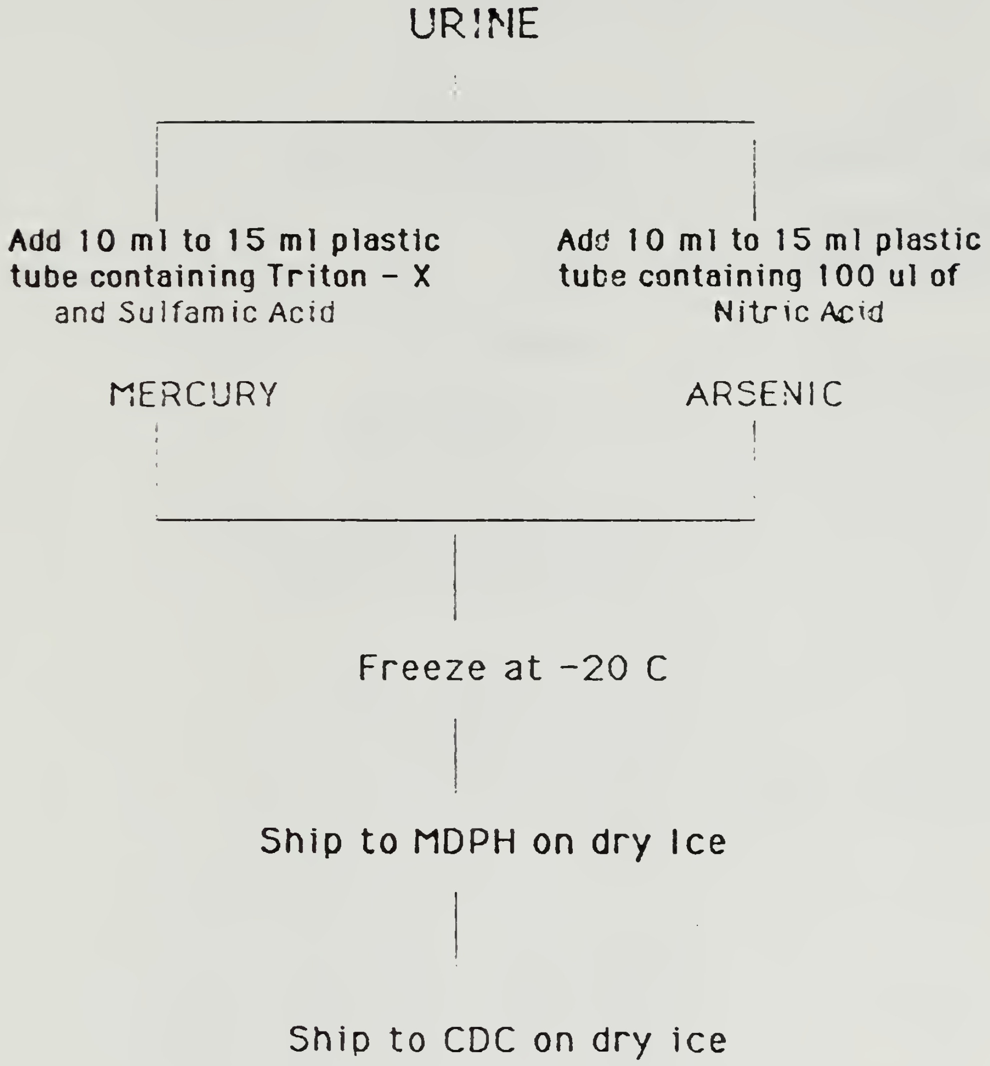
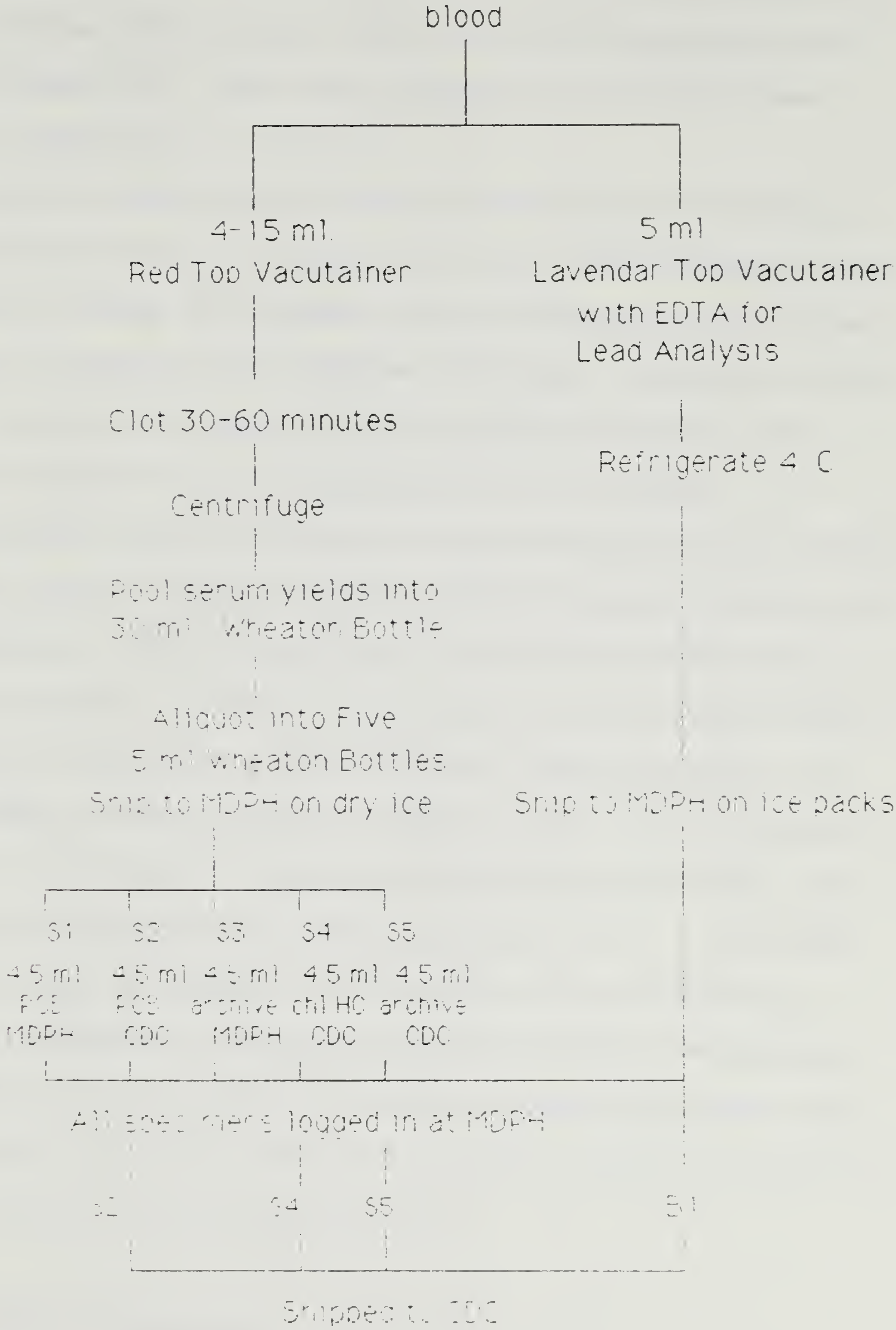

URINE
Add 10 ml to 15 ml plastic tube containing Triton - X and Sulfamic Acid
Add 10 ml to 15 ml plastic tube containing 100 ul of Nitric Acid
MERCURY
ARSENIC
Freeze at -20 C
Ship to MDPH on dry Ice
Ship to CDC on dry ice

FIGURE 7

BLOOD AND SERUM COLLECTION



Capillary column gas chromatography was used to measure specific PCB congeners in a group of 25 sera found by MDPH/CL to have the highest levels of PCBs in the New Bedford cohort. Data on chlorinated hydrocarbons are reported in Appendix GG. Data on PCB congeners will be reported when analyses are completed at a later date.

The accurate quantitation of PCBs is a challenging task because of the heterogeneity of PCBs, the changes that occur in these compounds during their transport through the ecosystem, and the differences in the response of instrument detectors to the invididual PCB isomers. Recently, attention has been focused on the accuracy of PCB quantitation in regard to the advantages of capillary gas chromatography (CGC) for component identification and regression analyses for quantitation (22, 23). Although CGC has been reported recently to provide improved accuracy, packed column gas chromatography (PCGC) was selected for quantitation in this study for the following reasons: 1) There was more experience with the PCGC method, and systematic biases could be controlled better compared with CGC. 2) The large number of serum PCB analyses (more than 1000) that were expected to be done in the study would require an enormous laboratory effort, and the time and cost required for CGC would be prohibitive. 3) The lesser accuracy that might be expected for an individual result by PCGC as compared with CGC would be offset by the added reliability and reproducibility of PCGC given the availability of well characterized control serums analyzed by PCGC. 4) PCGC accuracy can be further assessed efficiently by analyzing a subset of serum specimens by CGC.

Analysis of PCBs in human serum

The method used for quantitation of PCBs in serum is described in CDC

Laboratory Update 81-108, "Polychlorinated Biphenyl Determination at Parts-Per-Billion Level in Serum" (24), and in the detailed "Analysis Protocol for PCBs and Other Chlorinated Compounds of Environmental Concern: CDC - New Bedford Study," that is included in a condensed form as Appendix DD. This method is based on the work by Burse et al. (25) to quantitate PCBs in serum. Briefly, the method (Figure 5) consists of serum denaturation with methanol, solvent extraction, separation and concentration of compounds on activated silica gel, separation by gas chromatography, detection by electron capture, and quantitation by peak area integration. Quantitation of PCBs by peak areas was done by comparison of sample chromatograms with standard chromatograms for Aroclor 1254 (AR 1254) as described by Webb and McCall (26). PCB values are reported as parts per billion (ppb) PCB calculated as AR 1254 (ppb PCB as AR 1254).

In addition to the AR 1254 standards included in each chromatography run, an AR 1242 in vivo goat serum pool was included in all but five analytical runs. Quantitation of peaks eluting before DDE using the AR 1242 standard was also done as an alternative method of quantitation.

Experience of the MDPH Lab in the Analysis of PCBs

The MDPH/CL has considerable experience in the analysis of PCBs in human serum at the parts per billion level. During 1981-82, MDPH/CL participated in an interlaboratory study that was directed by CEH/CDC. Twenty-five laboratories (20 state and 5 private) of the 54 state/territorial and 117 private laboratories invited, participated in an assessment of the CDC proposed method to quantitate serum PCB levels in blood. Results of this study were published by Burse et al (27) in 1983.

Following participation in the CEH/CDC Collaborative Study, MDPH/CL

staff also gained experience through on-site training at CEH/CDC. During 1983, two analysts spent one week at the CDC laboratories receiving hands-on training in the analysis of serum PCBs. This experience enabled MDPH/CL to minimize interlaboratory differences for serum PCB analyses between their lab and CEH/CDC.

In addition to the Greater New Bedford Health Effects Study, the MDPH/CL has performed analyses for serum PCBs routinely including two other large surveys. During 1984, 90 residents of Norwood, Massachusetts, who lived near an industrial site with soil highly contaminanted with PCBs were tested for PCB levels in their serum. (28) In 1985, 57 serums from electrical workers for a Rhode Island company were analyzed for serum PCB levels. (29)

MDPH/CL also has experience in the analysis of PCBs in finfish, shellfish and environmental samples. PCB analyses for surveillance and regulatory programs have been done since 1981, and the types of samples tested include lobsters, bluefish, clams, surface wipes, water and retail food samples. Comparison of the results of the analysis of the same samples has shown good agreement among MDPH/CL, the federal Food and Drug Administration Laboratory (Region I, Boston), and the National Marine Fisheries Laboratory (Gloucester, MA).

Sample Handling Procedures

The procedures for collection, shipment, processing, and storage of serum and urine samples from study participants are described in detail in the "Specimen Collection and Shipping Protocol" (Appendix V). Handling of urine samples that were collected for shipment to CEH/CDC for analysis for metals are also described in Appendix V and Appendix BB. The procedures

related to serum specimens are briefly presented here.

Venous blood was collected from each participant into four, 15 ml red-top vacutainers and processed on site to remove the serum. For each individual a serum composite was made in a 30 ml hexane-rinsed Wheaton vial. Then 4.5 ml of the pooled serum was aliquoted into each of five-5ml labeled Wheaton vials that were stored at -20 C. The vials were labeled with the standard study identification number and a suffix of 1 to 5, and assigned for testing at the following laboratories:

Serum 1 (S1), PCB analysis at MDPH
S2, PCB analysis at CDC
S3, Archive sample at MDPH
S4, Chlorinated hydrocarbons analysis at CDC
S5, Archive sample at CDC.

Transport of serums between the New Bedford Study Clinic and the MDPH/CL and between MDPH/CL and CEH/CDC was done on dry ice in insulated shipping containers. The New Bedford/MDPH serum shipments went by messenger as needed. The MDPH/CDC shipments were sent by overnight mail (commercial or U.S. Post Office) on Mondays, Tuesdays or Wednesdays only as needed.

Serum samples were stored at -20 C until scheduled for analysis. Study samples were usually run in batches of 19 serums with appropriate controls.

Equipment and Reagents

Apparatuses: A Perkin-Elmer Sigma 2000 gas-liquid chromatograph equipped with a P-E model AS-300 automatic sampler and an Ni^{63} electron capture detector were used. The chromatograph was controlled and data

calculated and recorded by a Perkin-Elmer Model LCI-100 Integrator. A glass 6 foot X 1/8 inch (i.d.) column with 3% SE-30 on 80/100 mesh Gas Chrom Q was used for chromatography.

Reagents: The solvents used were N-hexane, methanol and ethyl ether and were pesticide grade quality (Burdick and Jackson). Sodium sulfate, used as a drying agent, was anhydrous, reagent grade (Fisher Scientific). Silica Gel, Woelm 70-150 mesh, was used as a preliminary separation and concentration medium to extract PCBs from serum.

PCB standards were supplied by CEH/CDC and were Monsanto Corporation Aroclor 1242, Lot KE-06-411 and Aroclor 1254, Lot AK38. These standards were used for calibration and supplied as stock solutions in iso-octane at concentrations of 0.1095 mg/ml for Aroclor 1242 and 0.2030 mg/ml for Aroclor 1254. Stock solutions were diluted with hexane to make working solutions of 134 ppb for AR 1242 and 141 ppb for AR 1254. Decachlorobiphenyl (DCB) Analabs Lot RCS-051, was used as an internal standard for quantitation. DCB was provided by CEH/CDC at a concentration of 0.0103 mg/ml and diluted with hexane to make a working solution of 51 ppb.

Extraction and Clean-up of PCBs from Human Serum

To accurately measure PCBs present in serum, it is necessary first to separate the PCBs from normal blood components and contaminants present in blood. Natural and man-made materials that may be found in blood can interfere with the detection, identification, and quantitation of PCBs. The procedure for extraction and clean-up, detailed in Appendix DD, is described here. Usually 19 study serum samples were processed at one time. Each serum specimen was mixed with methanol and after centrifugation, the

PCB-containing supernatant was withdrawn. The serum was extracted two more times and the extracts combined. Each pooled extract was concentrated by a nitrogen stream and then passed through a small (18 cm x 9 mm) glass column that contained silica gel sandwiched between two anhydrous sulfate layers. The portion of the effluent from the silica gel column that was retained (15 ml following the first 7 ml washed through the column with hexane) was stabilized with paraffin and evaporated to near dryness with a gentle flow of nitrogen. The concentrate was reconstituted with a one ml volume of the internal standard (DCB), and was then ready for analysis by gas chromatography electron capture.

Gas Chromatography Electron Capture Analysis of Serum Extracts

Nineteen samples were analyzed in a set defined as an analytical run. An analytical run was comprised of 19 serum extracts, five quality control serum extracts and nine calibration standards. Samples were automatically injected and data recorded by laboratory microprocessor instrumentation that produced a hard copy chromatogram, or picture of the gas chomatography. Examples of the analytical output are shown in the graphs in Appendix EE that depict an AR 1254 calibration standard, a low PCB level quality control sample, a high PCB level quality control standard, a low PCB level study sample and a high PCB level study sample. Gas chromatography of one analytical run containing 19 study samples, standards and controls took approximately 22 hours.

Quantitation of PCBs present in human serum samples was determined by the CDC method procedure based on the Webb and McCall method. As discussed earlier, all samples were quantitated in reference to AR 1254 and reported as parts per billion AR 1254. Samples were also quantitated as parts per

billion AR 1242 as an alternate measure of exposure.

Quality Assurance of the Laboratory Analyses

Quality assurance of laboratory analyses for PCBs was achieved by three means, which are described in detail in the "Analysis Protocol for PCBs and Other Chlorinated Compounds of Environmental Concern: CDC - New Bedford Study" (Appendix DD) and "Quality Control Report from CEH/CDC" (Appendix KK).

1. The comparability of MDPH/CL and CEH/CDC was established through replicate analyses of the same series of known samples, in vitro and in vivo spiked pools. Criteria were established based on the target (average) values obtained.

   a. For control samples over 20 ppb, MDPH/CL results must be within 15% of the target value and the CDC mean.

   b. For control samples less than 20 ppb, MDPH/CL results must be within 25% of the target value and the CDC mean.

   c. For control samples over 20 ppb, MDPH/CL coefficient of variation must be less than 15%.

   d. For control samples less than 20 ppb, MDPH/CL coefficient of variation must be less than 25%.

2. Quality control limits were established for each laboratory, and quality control rules (decision criteria) were defined to reject analyses when limits were exceeded. The analytical system would be declared "out-of-control" if any one of three events occurred either singly or in combination, and analyses would continue only after review and discussion of the analytical situation with CEH/CDC.

   a. If the values for quality control samples obtained during a

single analytical run fall outside the 99% confidence limits established for the control samples.

b. If two consecutive values of the same control sample fall either above or below the 95% confidence limits for that control sample.

c. If 10 consecutive values for the same control sample fall either above or below the mean value of the control sample.

3. CEH/CDC analyzed a subset of the specimens analyzed by CL/MDPH and comparability of results was monitored throughout the study.

Quality control was maintained by including five quality control samples in every analytical run. These quality control samples included: a low or high bench control serum (prepared in vivo), a low or high external control serum (prepared in vivo), a base bovine serum, a chlorinated hydrocarbon serum (prepared in vitro), and an AR 1242 control serum (prepared in vivo). A calibration standard was analyzed prior to the initiation of sample analysis. If the chromatography pattern or the response factors for known peaks were inadequate, the analytical run would not be started. When the calibration standard showed characteristic peaks and response levels, an analytical run was initiated in which a calibration standard was inserted between every four serum extracts to check chromatography patterns and update the calibration standard in the integrator.

Each analytical run included a low or high "external" control serum that was inserted by the Laboratory Data and Sample Coordinator to a randomly selected position in a rack of samples that were scheduled for an analytical run. The Coordinator, in consultation with the Study Project Director and Laboratory Director, would select the study serum samples for analysis in analytical runs. These samples would be placed in a test tube

rack along with the external control sample and delivered to the laboratory analyst.

Samples were queued into the automatic sampler in even-numbered positions and vials containing hexane were inserted at the odd-numbered positions to avoid a carry-over effect from samples with a high concentration of PCBs. These hexane-containing vials provided a wash cycle for the automatic sample injector.

Serum PCB Levels Calculated as Parts Per Billion Aroclor 1242

Serum PCB concentrations were calculated as ppb Aroclor 1242 as well as in ppb AR 1254 to ensure that any significant recent exposures would not be underestimated. An Aroclor 1242 calibration standard and quality control serum were used as the basis for identifying Aroclor 1242 chromatographic patterns and for quantitation (See Laboratory Methods). The prevalence estimate of elevated serum PCB levels using AR 1242 values did not identify appreciably more persons other than those already identified using the AR 1254 quantitation values (Appendix HH). Therefore, reported values for serum PCB levels were expressed as AR 1254 to maintain clarity without sacrifice of accuracy.

Sample Collection Methods

The following sections describe the laboratory procedures that were followed in the Greater New Bedford PCB Health Effects Study Clinic for the proper collection, processing, storage and shipment of physiologic specimens from the study subjects. Procedures were strictly followed to avoid contamination, loss, or degradation of the specimens. A schedule was established for collecting a specimen in which a 12 hour fast requirement

preceeded the phlebotomy appointment. Blood-drawing occurred in the study clinic or in participants' homes when necessary. An aseptic phlebotomy technique was maintained at all sites.

Blood and urine collection and processing were performed under carefully controlled conditions. Serum separation took place on site in the clinic laboratory. Glassware used (e.g. pipets, storage vials) had been cleaned with acetone and hexane.

The subjects were given specific instructions in either English or Portuguese to ensure proper collection of urine specimens and to avoid potential contamination from ambient air, contact with any parts of the body, clothing, or external surfaces. Urines were processed on site at the clinic laboratory under a fume hood. The urines were processed within 1/2 hour of collection. On rare occasions, urine specimens that were not processed immediately were refrigerated promptly at 4° to 8° C and the delay in processing of these specimens was noted.

During pilot testing of the blood collecting procedures, a multiple sample needle was compared to a butterfly needle. After pilot testing of the butterfuly needle with Lue-adapter, these phlebotomy instruments were found to be awkward for the phlebotomist and more painful to the subject. Therefore, standard vacutainer needles and tubes were used throughout the study.

At the beginning of each day when a respondent was scheduled for an appointment, a "Urine Laboratory Blank" was prepared according to study protocol, that substituted deionized water instead of urine. A preprinted "Lab Blank" label was placed on each Arsenic and Mercury analysis tube. The blanks were frozen upright at -20° C.

In March, 1986, two sets of "Serum Lab Blanks" were prepared. Two

sets of four vials each (e.g., two screw top, two crimp top Wheaton vials) were sent to MDPH/CL. One set of vials was subsequently sent to CEH/CDC. All specimens as well as "Serum Lab Blanks" and "Urine Laboratory Blanks" were transported by an MDPH employee to MDPH/CL in Boston. Messenger delivery of the specimens never took more than 85 minutes. Serum samples destined for the CEH/CDC were checked against the shipping manifest that was prepared in New Bedford. All shipments to CEH/CDC were sent via overnight courier.

All records associated with each subject's specimens were maintained to ensure that all information was properly collected and accurate. All specimens were labeled promptly to avoid label record errors on the subject's specimen. A list of computer codes for comment section of the shipping manifest was designed. This allowed for consistency in coding all deviations from the protocol for specimen collecting, processing and storage.

The specimens from each subject were packed upright and secure in a styrofoam shipper with bubble pack material, serum specimen freezer boxes with dividers, and urine tube freezer boxes with dividers. Frozen ice packs were placed at the bottom and top of the shipper and stored with the cover off in the freezer overnight preceding a shipment to the MDPH/CL Whole blood specimens were kept separate and shipped in a smaller styrofoam shipper equipped with a cold pack. Each shipment was accompanied by a complete, numbered manifest. A copy of the manifest was kept at the clinic laboratory to ensure against loss and to serve as a record of all specimens collected.

DATA ANALYSIS

The purposes of Phase I of the Greater New Bedford PCB Health Effects Study were:

- To determine the prevalence of elevated serum PCB levels in the local population, and to identify 150 individuals with serum PCB levels $\geq$ 30 ppb to participate in the Phase II clinical investigation.
- To investigate the possible association of serum PCB levels with blood pressure readings in study subjects. (Note: On the basis of a review of the literature, extraneous variables (e.g. residential and occupational histories, dietary habits, health status and demographic characteristics were collected).

Therefore, the data analysis strategies were directed towards a description of the pertinent variables (e.g., serum PCB levels, seafood consumption, occupational histories, health status, blood pressure readings and selected demographic characteristics). In addition, if patterns were found among correlational data, appropriate models would be designed to highlight predictive relationships among independent variables (e.g., diastolic blood pressure readings, age, body weight) and the dependent variable (e.g., serum PCB level).

A generic statistical strategy was applied to the study's data. The strategy included four steps that thoroughly investigated relationships among and between all variables. First, descriptive statistics (e.g., means, standard deviations, ranges, medians, quartile analyses) were applied to provide an overall picture of the sample from the Greater New Bedford area and subsequently, a comparison with the total population. Also, the descriptive statistics provided an overview of interval level

variables such as blood pressure readings and other selected demographic variables such as age. Chi-square tests for differences were utilized for selected data.

Second, bivariate relationships between groups were explored. These included differences in serum PCB levels and participation rates in the Portuguese versus non-Portuguese groups, females versus males, as well as differences between means of blood pressure readings (both systolic and diastolic readings) taken at three time points during data collection. These data also provided indications of strata that may or may not be utilized in univariate and multivariate modeling.

Third, correlation matrices were run on variables of interest, based on a review of the literature as well as the descriptive variables (i.e., systolic/diastolic blood pressure readings, age, body mass, PCB serum levels). These correlations demonstrated patterns and trends for the prevalence sample and the enrichment sample. In addition, the correlations provided a basis for choosing modeling designs.

Fourth, several univariate and multivariant models were attempted. Multiple regression models were used to confirm relationships demonstrated in the correlation matrices. In addition, several multiple regression and covariance models were attempted by using variables found to be significant predictors from previous studies. However, none of the models demonstrated significant predictive relationships between the independent variables (e.g., systolic/diastolic blood pressure readings, age, body mass) and the dependent variable (e.g., serum PCB levels). The variables were also placed in a logistic regression to stabilize weights of the predictors; however, these models were not significant as well.

All data were coded and key punched on an IBM mainframe at the

Massachusetts Department of Public Health. All data entries were extensively edited and cross verified to insure accuracy. The statistical package applied to these data was the Statistical Analysis System (SAS) (1982). This all-purpose data analysis system provides information storage and retrieval, data modification and programming, statistical analysis, file handling, and report writing (SAS, 1982, p. III).

LIMITATIONS

The design of the Greater New Bedford PCB Health Effects Study was a cross sectional random sample, stratified by age and sex in order to determine prevalence. Because of the response rate (57%), it may be possible that non-participants differed greatly from participants and that the results do not reflect an accurate assessment of PCB exposure in Greater New Bedford. The development and usage of the refusal questionnaire was helpful in assessing characteristics of non-participants. However, questions in the refusal questionnaire were necessarily broad and can be used only to make general assumptions about the refusal population. In addition, the refusal questionnaire was administered in a less regulated manner and via different means (i.e., mostly by telephone or through the mail) and to a population, by definition, less willing to cooperate.

It should also be noted that this investigation was conducted several years after the various fishing bans went into effect. Seafood consumption patterns may have changed over the 7-year period that the ban has been in effect and may thus complicate conclusions being drawn regarding the effects of contaminated seafood consumption on serum PCB level.

Although strong emphasis was placed on quality control of survey data obtained from the interviews, it is possible that the quality of

information collected varied from interviewer to interviewer. In all, five individuals served as interviewers for this investigation. The interviews were conducted in Spanish, English and Portuguese. It is important to note that these interviews were administered tri-lingually, and therefore variation in the execution of survey questions was a strong possibility. However, all interviewers received identical training and were assessed before they entered the field settings.

One of the major limitations of a cross-sectional epidemiological investigation regards polarization (i.e., groups of people moving into a specific area for unknown periods of times) within the study area. However, in this study, every resident was randomly selected and a minimum age and residency requirement was set. As a result, no residents were allowed admission into the study if they had recently moved into the study area.

HUMAN SUBJECTS PROTECTION

Before the initiation of field operations in the Greater New Bedford area, the study protocol was presented to the Human Subject Review Committee at the Lemuel Shattuck Hospital in Boston, Massachusetts. All Massachusetts Department of Public Health proposals are submitted to this committee for ethical and other considerations. The committee voted to approve the study protocol on May 24, 1984 (Appendix CC). Confidentiality of information supplied by study participants was maintained by assigning coded identification numbers. Identifying information was stored in locked file cabinets located at the field office in New Bedford. The field office was protected by a sensory alarm system. Upon entering the study office, each participant was asked to review and sign a statement of informed

consent (Appendix K). Each participant was informed that they could refuse to answer specific questions or withdraw from the study at any time during the course of the interview.

CHAPTER III

RESULTS

The purpose of the Greater New Bedford Health Effects Study (GNBHES) was to determine the prevalence of elevated serum PCB levels among a group of randomly selected residents, and to test the hypothesis that serum PCB level is associated with measurement of diastolic blood pressure. Phase I also sought to identify 150 individuals with serum PCB levels $\geq$ 30 ppb in order to proceed to Phase II.

This chapter presents the results of a number of descriptive analyses within the two samples studied (prevalence and enrichment), and subgroups within the respective samples. A series of bivariate relationships are examined, as well as a review of correlational patterns and trends. Statistical models (e.g., multiple regression, stepwise regression, etc.) are used where both appropriate and applicable. In addition, the results of the random selection and the results of analyses of refusal questionnaire data are both presented.

PREVALENCE

Participation Rates

The participation rate was calculated by using only eligible individuals who had been contacted by a staff person (i.e., participants and refusers). Overall, 57% of eligible randomly selected candidates agreed to participate and completed the interview and laboratory testing. The participation rate varied little with age, sex, and residence. Chi square tests for differences in participation were performed for each variable (i.e., age, sex and residence). Age was significantly associated

with participation for females (x^2 = 11.865 with 4 d.f. p = .018). However, other observed variations were not statistically significant (Table 2).

Characteristics of the Participant Sample

Although the City of New Bedford was significantly oversampled and Fairhaven, Acushnet, and Dartmouth were only slightly undersampled (Table 3), when the sample was stratified by age and sex, it is evident that, with few exceptions, is representative of the four town area (Table 4). The participant sample was also compared to federal census data for a number of other demographic characteristics such as industry of employment, education and ethnicity (Portuguese or non-Portuguese). The census figures were five years old when study data collection began. In some instances, these census data are not comparable, so these findings are presented only for general comparison and should be interpreted with caution.

In general, the participant population was similar to what was reported in the federal census with regard to industry of employment. The participant sample contained an average of 8.5% more Portuguese persons on a town to town basis and contained an average of 15.5% more high school graduates and 7.5% more college graduates. The federal census bases its estimates on total population figures for ethnicity and on persons 25 and older for education. The inclusion of persons younger than 18 (in the case of ancestry) and persons older than 64 (in both cases) may have had a dilutional effect on the numbers. In addition, the observed figures are indicative of a population in change and concur with past trends.

Table 2.

Participation Rates

		MALES			FEMALES		
		SELECTED	PARTICIPATED	%*	SELECTED	PARTICIPATED	%
New Bedford							
AGES:	18 - 24	89	47	52.8	92	50	54.3
	25 - 34	126	73	57.9	151	92	60.9
	35 - 44	99	52	52.5	104	61	58.6
	45 - 54	88	58	65.9	86	54	62.8
	55 - 64	90	46	51.1	148	73	49.3
	Don't Know	1	-	-	1	-	-
	ALL	493	276	56.0	582	330	56.7
Dartmouth							
AGES:	18 - 24	20	11	55.0	17	10	58.8
	25 - 34	15	9	60.0	17	10	58.8
	35 - 44	29	16	55.2	29	20	69.0
	45 - 54	29	15	51.7	18	10	55.5
	55 - 64	26	13	50.0	23	12	52.2
	ALL	119	64	53.8	104	62	59.6
Fairhaven							
AGES:	18 - 24	9	3	33.3	6	5	83.3
	25 - 34	15	9	60.0	20	18	90.0
	35 - 44	12	9	75.0	6	5	83.3
	45 - 54	13	3	23.1	13	4	30.8
	55 - 64	14	10	71.4	10	4	10.0
	ALL	63	34	54.0	55	36	65.5
Acushnet							
AGES:	18 - 24	7	3	42.9	5	4	80.0
	25 - 34	12	7	58.3	5	4	80.0
	35 - 44	2	2	100.0	10	9	90.0
	45 - 54	7	2	28.6	3	2	66.6
	55 - 64	3	3	100.0	5	2	49.0
	Don't Know	1	-	-	-	-	-
	ALL	32	17	53.1	28	21	75.0
	TOTAL	707	391	55.3	769	449	58.4

* % IS PERCENT OF PEOPLE SELECTED WHO PARTICIPATED

Table 3.

Total Expected and Observed Participation by City/Town

	Expected n	Actual n	X^2	p
New Bedford	550	606	5.711	.0169*
Dartmouth	146	126	2.7397	.0979
Fairhaven	92	70	7.348	.0067*
Acushnet	52	38		
TOTAL	840	840		

(expected values were calculated from 1980 federal census data.)

Table 4.

Expected vs. Observed
Participant Sample by Age, Sex and Residence

	Males		Females	
	Pe*	Po+	Pe*	Po+
New Bedford	n	n	n	n
Total	256	276	294	330
18-24	55	47	61	50
25-34	64	73	68	92**
35-44	40	52	46	61***
45-54	45	58	52	54
55-64	52	46	66	73
Dartmouth				
Total	71	64	75	62
18-24	16	11	16	10
25-34	16	9	17	10
35-44	13	16	14	20
45-54	13	15	13	10
55-64	13	13	15	12
Fairhaven				
Total	45	34	47	36
18-24	9	3	8	5
25-34	11	9	12	18
35-44	8	9	8	5
45-54	8	3	9	4
55-64	9	10	10	4
Acushnet				
Total	26	17	26	21
18-24	5	3	4	4
25-34	6	7	6	4
35-44	5	2	6	9
45-54	5	2	5	2
55-64	5	3	6	2

*Expected number of participants from age group [1].
+Observed number of participants from age group.

**Indicates statistical significance at $p \leq .01$
***Indicates statistical significance at $p \leq .05$

[1] Expected rates are based on % contribution of each age, sex and town group according to the 1980 federal census data.

PCB Level

The alternate quantitation of PCBs as pre DDE Aroclor 1242 resulted in low levels of serum PCBs with only two individuals exceeding 30 ppb (Appendix HH). Further discussion of PCB serum levels will be restricted to Aroclor 1254 Quantitation only. Table 5 and Figure 8 present the distribution of serum PCB levels as Aroclor 1254 among participants of the Prevalence Study for males, females, and the total prevalence population. Only 1.3% of the total study group (n = 840) had serum PCB levels greater than or equal to 30 ppb (the CDC estimate of an elevated serum PCB level). This same percentage was observed among the male (n = 391) and female (n = 449) prevalence study groups (mean levels were 5.9 ppb and 5.8 ppb respectively) when stratified by sex.

The range in serum PCB levels for the total prevalence group was 0.38 to 154.2 ppb. The range among females was 0.38 to 154.2 ppb and among males the the observed range was 0.50 to 60.92 ppb.

Serum PCB Level by Reported Ethnicity

Table 6 presents variations in serum PCB levels among Portuguese/Cape Verdean and Non-Portuguese/Cape Verdean males. Slightly higher mean and median levels were observed among males of Portuguese or Cape Verdean descent (6.76 ppb vs. 4.76 ppb and 4.63 ppb vs. 3.58 ppb).

Similar differences were observed among female prevalence participants. Table 7 shows the serum ppb range as well as the mean, median and standard deviation among Portuguese/Cape Verdean (n = 208) and Non-Portuguese/Cape Verdean females (n = 241). The range in serum PCB level among Portuguese/Cape Verdean was 0.85 to 154.2 ppb with a median of 4.41 ppb, the range for non-Portuguese/Cape Verdean was 0.38 to 45.88 ppb

TABLE 5.

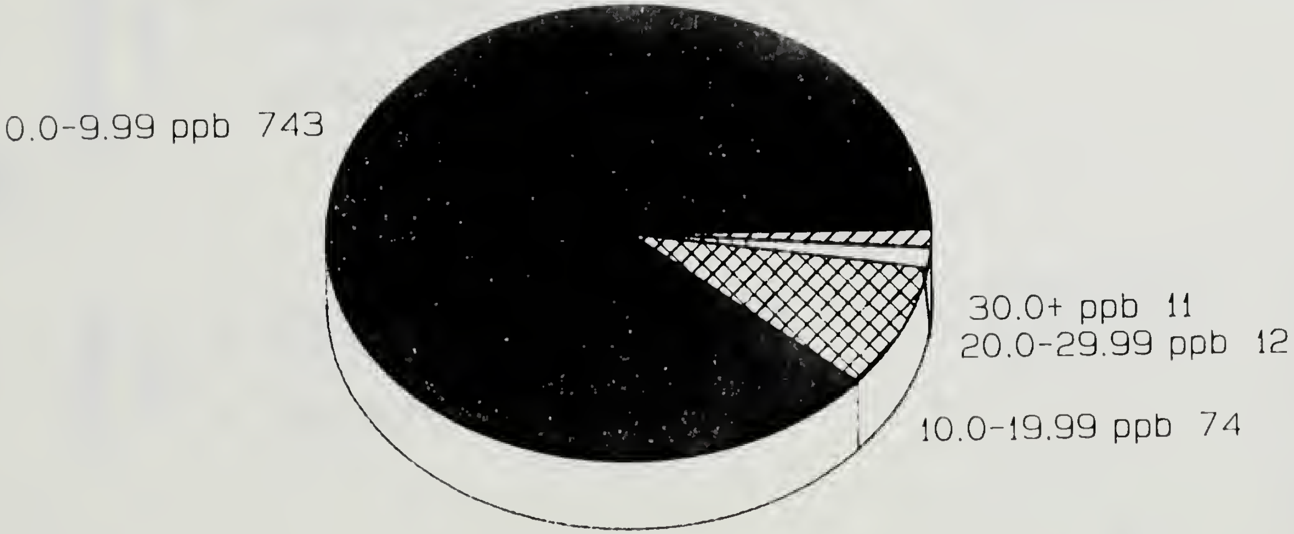
Distribution of Serum PCB Levels
Prevalence

Serum PCB Level*	Males		Females		Total	
	n=391		n=449		n=840	
	n	%	n	%	n	%
0.0 - 1.49	30	7.8	26	5.8	56	6.7
1.5 - 2.99	93	23.8	120	26.7	213	25.4
3.0 - 4.49	91	23.3	111	24.7	202	24.1
4.5 - 5.99	62	15.9	63	14.0	125	14.9
6.0 - 7.49	24	6.1	40	8.9	64	7.6
7.5 - 8.99	27	6.9	30	6.7	57	6.8
9.0 - 10.49	18	4.6	20	4.5	38	4.5
10.5 - 11.99	4	1.0	10	2.2	14	1.7
12.0 - 13.49	10	2.6	3	.7	13	1.5
13.5 - 14.99	7	1.8	3	.7	10	1.2
15.0 - 16.49	4	1.0	3	.7	7	.8
16.5 - 17.99	6	1.5	6	1.3	12	1.4
18.0 - 19.49	1	.3	3	.7	4	.5
19.5 - 20.99	4	1.0	1	.2	5	.6
21.0 - 22.49	2	.5	1	.2	3	.4
22.5 - 23.99	2	.5	2	.5	4	.5
24.0 - 25.49	-	-	1	.2	1	.1
25.5 - 26.99	-	-	-	-	-	-
27.0 - 28.49	-	-	-	-	-	-
28.5 - 29.99	1	.3	-	-	1	.1
30+	5	1.3	6	1.3	11	1.3
NEXT TO HIGHEST		45.68		61.72		61.72
HIGHEST		60.92		154.20		154.20
MEAN		5.92		5.77		5.84
MEDIAN		3.88		3.88		3.88
STANDARD DEVIATION		6.24		8.92		7.78
25TH		2.68		2.63		2.67
75TH		6.83		6.44		6.65

*PCB measured in parts per billion.

FIGURE 8

DISTRIBUTION OF AROCLOR 1254 SERUM LEVEL PREVALENCE DATA n=840



pcb measured in parts per billion

Table 6.

Distribution of Serum PCB Portuguese/Cape Verdean vs. Non-Portuguese/Cape Verdean Prevalence

Males

	Portuguese		Non-Portuguese	
	n=207		n=184	
Serum PCB Level*	n	%	n	%
0.0 - 1.49	14	6.8	16	8.7
1.5 - 2.99	46	22.2	47	25.5
3.0 - 4.49	41	19.8	50	27.2
4.5 - 5.99	32	15.5	30	15.9
6.0 - 7.49	8	3.9	16	8.7
7.5 - 8.99	20	9.7	7	3.8
9.0 - 10.49	13	6.3	5	2.7
10.5 - 11.99	3	1.5	1	.5
12.0 - 13.49	6	2.9	4	2.2
13.5 - 14.99	5	2.4	2	1.1
15.0 - 16.49	3	1.5	1	.5
16.5 - 17.99	5	2.4	1	.5
18.0 - 19.49	-	-	1	.5
19.5 - 20.99	3	1.5	1	.5
21.0 - 22.49	2	1.0	-	-
22.5 - 23.99	2	1.0	-	-
24.0 - 25.49	-	-	-	-
25.5 - 26.99	-	-	-	-
27.0 - 28.49	-	-	-	-
28.5 - 29.99	-	-	1	.5
30 +	4	1.9	1	.5
HIGHEST		45.68		60.92
NEXT TO HIGHEST		38.85		29.52
MEAN		6.76		4.96
MEDIAN		4.63		3.58
STANDARD DEVIATION		6.66		5.63
25TH PERCENTILE		2.84		2.50
75TH PERCENTILE		8.76		5.66

*PCB measured in parts per billion.

Table 7.

Distribution of Serum PCB
Portuguese/Cape Verdean vs. Non-Portuguese/Cape Verdean
Prevalence

Females

	Portuguese		Non-Portuguese	
	n=208		n=241	
Serum PCB Level*	n	%	n	%
0.0 - 1.49	10	4.8	16	6.6
1.5 - 2.99	53	26.4	67	27.8
3.0 - 4.49	42	20.2	69	28.6
4.5 - 5.99	31	14.9	32	13.3
6.0 - 7.49	18	8.7	22	9.1
7.5 - 8.99	19	9.1	11	4.6
9.0 - 10.49	10	4.8	10	4.2
10.5 - 11.99	7	3.4	3	1.2
12.0 - 13.49	2	1.0	1	.4
13.5 - 14.99	2	1.0	1	.4
15.0 - 16.49	2	1.0	1	.4
16.5 - 17.99	3	1.4	3	1.2
18.0 - 19.49	2	1.0	1	.4
19.5 - 20.99	-	-	1	.4
21.0 - 22.49	1	.5	-	-
22.5 - 23.99	1	.5	1	.4
24.0 - 25.49	-	-	1	.4
25.5 - 26.99	-	-	-	-
27.0 - 28.49	-	-	-	-
28.5 - 29.99	-	-	-	-
30 +	5	2.4	1	.4
HIGHEST		154.20		45.88
NEXT TO HIGHEST		61.72		24.46
MEAN		6.85		4.87
MEDIAN		4.41		3.71
STANDARD DEVIATION		12.10		4.49
25TH PERCENTILE		2.76		2.52
75TH PERCENTILE		7.55		5.86

*PCB measured in parts per billion.

with a median of 3.71 ppb.

Serum PCB Level and Age

Figure 9 shows the relationship of serum PCB level to age among prevalence participants (n = 840). In the five age groups into which participants were categorized (i.e., 18-24, 25-34, 35-44, 45-54, 55-64) the mean serum PCB levels were: 2.59, 3.84, 5.30 8.18 and 8.96 ppb respectively.

Serum PCB Level by Age, Sex and Residence

Serum PCB level was examined in relation to age, sex and residence for prevalence participants (n = 840). The range in serum PCB levels are presented as well as the mean, median and standard deviation for each subgroup. These data are presented in Table 8. It should be noted that the data broken down by city and town do not yield sufficient statistical power to determine differences in serum PCB levels within each of these sub-categories.

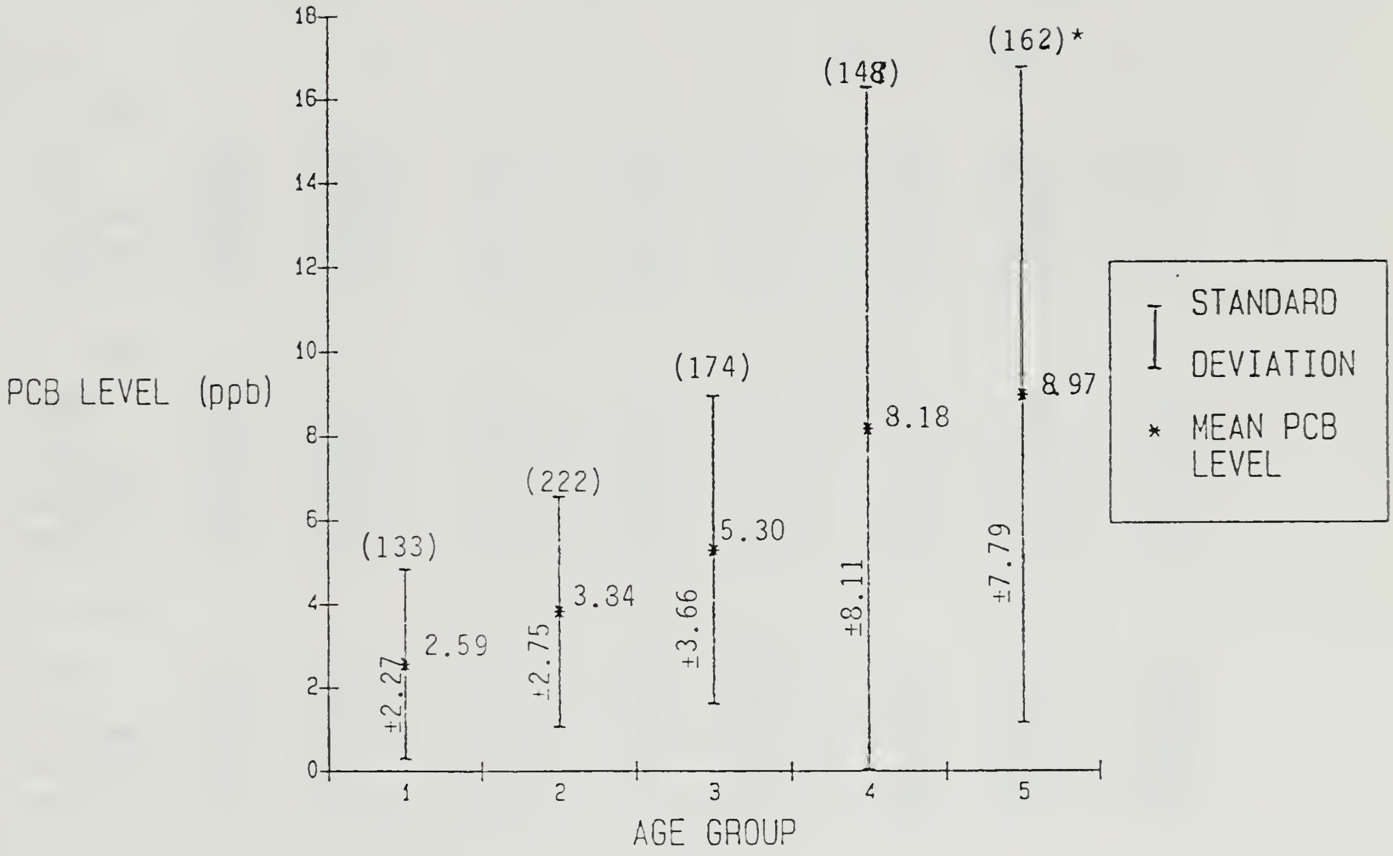
Seafood Consumption

The relationship of serum PCB level to fish consumption is an area of great concern both in the Greater New Bedford area and elsewhere. It has been noted that seafood consumption is the primary source of PCB exposure in the United States today. (13) This finding has been a particular concern in the Greater New Bedford area due to the massive PCB contamination of local seafood species over and above that of the fish in the general commercial marketplace. For this reason an extensive amount of information on fish consumption was collected for both general and locally

FIGURE 9

MEAN and STANDARD DEVIATION
SERUM PCB LEVEL[1] by AGE GROUP

PREVALENCE



( ) = number of persons in age group

1 = 18-24 years old
2 = 25-34 years old
3 = 35-44 years old
4 = 45-54 years old
5 = 55-64 years old

* One outlier was eliminated as the level was more than twice the second highest.

[1] PCB measured in parts per billion

Table 8.

Serum PCB Levels* by Residence, Age and Sex
Mean and Standard Deviation, Range and Median
Prevalence

	New Bedford n = 606		Dartmouth n = 126		Fairhaven n = 70		Acushnet n = 38	
Age	M	F	M	F	M	F	M	F
18 - 24								
Mean	2.44	2.63	2.90	3.30	2.24	2.66	2.21	1.89
S.D.	2.90	2.17	1.15	1.48	1.33	0.71	0.83	0.52
Minimum	0.50	0.85	1.53	1.23	0.92	1.62	1.28	1.31
Maximum	21.05	14.32	5.62	5.50	3.58	3.61	2.88	2.53
Median	1.71	2.12	2.58	3.55	2.22	2.71	2.48	1.85
25 - 34								
Mean	4.12	3.74	3.52	3.94	3.60	4.00	3.09	2.82
S.D.	3.91	2.03	2.09	2.75	1.78	1.60	0.66	0.53
Minimum	0.75	0.38	1.47	0.94	0.74	1.63	2.07	2.35
Maximum	29.53	10.49	7.78	9.21	6.45	7.31	3.74	3.50
Median	3.00	3.34	2.99	2.85	3.57	3.89	3.52	2.71
35 - 44								
Mean	5.76	4.91	5.30	4.21	6.28	6.34	13.11	4.49
S.D.	4.69	3.04	2.60	2.31	2.77	1.59	10.92	2.66
Minimum	0.99	1.16	1.39	0.99	3.59	5.03	5.39	1.39
Maximum	21.44	17.23	9.86	9.96	12.11	8.66	20.84	10.32
Median	3.74	3.89	5.18	3.77	6.41	5.35	13.11	4.51
45 - 54								
Mean	8.98	7.06	9.22	9.74	8.79	7.14	5.09	3.82
S.D.	9.64	5.34	8.18	12.96	5.08	6.71	4.49	0.08
Minimum	1.09	1.55	4.16	2.54	3.42	2.72	1.92	3.76
Maximum	60.92	30.55	36.61	45.88	13.51	17.13	8.27	3.88
Median	5.57	5.31	6.83	6.12	9.43	4.35	5.09	3.82
55 - 64								
Mean	8.74	11.61	11.33	7.31	5.35	9.47	5.56	7.12
S.D.	7.07	19.26	8.75	2.28	1.01	6.05	0.61	3.41
Minimum	1.71	1.95	2.68	3.30	3.99	3.28	5.12	4.71
Maximum	45.68	154.20	36.06	12.58	6.84	15.63	6.25	9.53
Median	6.88	6.96	9.56	7.54	5.32	9.49	5.30	7.12

*PCB measured in parts per billion

caught seafood. A map of the local areas of harbor/estuary contamination was shown to the respondents to make sure that each was using the same local boundaries to identify fishing areas. Consumption of locally caught species was of special interest in determining how serum PCB level might be affected.

Seafood Source

The most frequently mentioned source from which people obtain seafood is fish retailers (Table 9). Over half of Greater New Bedford obtains fish from this source alone. When combined with supermarkets and restaurants, it accounts for 78.2% of all seafood. This number is in sharp contrast to the 12.9% of the population who obtain fish by catching it themselves or from a family or friend who has caught it. This pattern has not changed appreciably from past years (Table 10). Ten years ago, slightly over half (52.1%) of Greater New Bedford residents obtained their fish primarily from local retailers, and when combined with supermarkets and restaurants, they accounted for 73.6% of all primary seafood sources. Similarly, only a small percentage of people (14.8%) obtained their seafood by catching their own or from a family member or friend who had caught it.

Looking specifically at sources of seafood caught and consumed from locally contaminated areas, most people (61.5%) report that they do not currently consume this seafood (Tables 11 and 12). This response is somewhat similar (56.6%) to that of past sources of local seafood before the fishing closure took effect. This number would indicate that even before the general discovery of the massive contamination problems, the majority of the general public in the Greater New Bedford area was not directly or knowingly catching and eating fish from these areas. Among

Table 9.

Present Source of General Seafood

Primary Source of Fresh Seafood Today:	Prevalence n = 840	Enrichment n = 110
	Percent of participants	
CATCH OWN	4.2%	34.5%
FAMILY/FRIENDS CATCH	8.7	6.4
LOCAL FISHERMEN	6.9	8.2
FISH RETAILERS	54.3	40.9
SUPERMARKETS/GROCERY	14.1	6.4
RESTAURANTS	9.8	3.6
GOT NONE	2.0	-
DON'T KNOW	-	-

Table 10.

Past Source of General Seafood

Primary Source of Fresh Seafood Ten Years Ago:	Prevalence n = 840	Enrichment n = 110
	Percent of participants	
CATCH OWN	5.2%	44.5%
FAMILY/FRIENDS CATCH	9.6	5.5
LOCAL FISHERMEN	5.2	7.3
FISH RETAILERS	52.1	35.5
SUPERMARKETS	12.1	5.5
RESTAURANTS	9.2	.9
GOT NONE	4.6	-
DON'T KNOW	1.7	.9

Table 11.

Present Source of Local Seafood

Primary Source of Local Seafood Today:	Prevalence n = 840	Enrichment n = 110
	Percent of participants	
CATCH OWN	6.4%	52.7%
FAMILY/FRIENDS CATCH	9.0	13.6
LOCAL FISHERMEN	.8	-
FISH RETAILERS	10.9	10.0
SUPERMARKETS/GROCERY	2.5	-
RESTAURANTS	2.4	.9
GOT NONE	61.5	20.9
DON'T KNOW/MISSING	6.4	1.8

Table 12.

Past Source of Local Seafood

Primary Source of Local Seafood Ten Years Ago:	Prevalence n = 840	Enrichment n = 110
	Percent of participants	
CATCH OWN	9.0%	62.7%
FAMILY/FRIENDS CATCH	11.5	10.9
LOCAL FISHERMEN	.4	-
FISH RETAILERS	11.3	10.9
SUPERMARKETS/GROCERY	2.5	-
RESTAURANTS	1.8	-
GOT NONE	56.6	12.7
DON'T KNOW	6.9	2.7

persons who do currently eat or who have ever eaten locally caught seafood, catching one's own or having a family/friend catch the fish is mentioned as the most frequent source, i.e., 15.4% presently compared to 20.5% 10 years ago. There would appear to be a slight drop in local seafood consumption in the past 10 years.

Trends in seafood consumption

Among the general population (i.e., prevalence participants) of Greater New Bedford overall fish consumption has only decreased among 12.9% of the people. In contrast, 87.1% report either similar or higher consumption levels over the past 10 years (Table 13). This finding is in sharp contrast to that for trends in local fish consumption which show that people who are or have been local fish consumers, most (61.1%) have decreased their consumption, while 36.3% report equivalent or increased trends.

Preferred species

A number of species have been identified as being likely to have PCB residues if they are taken from contaminated areas. These have been identified by the U.S. Food and Drug Administration (FDA) and others. Table 14 presents a summary of these particular species and the percent of people who consume these. Although these results indicate a range in popularity, some percentage of the prevalence participants does consume each of these species. Comparing frequency of consumption of thse species when obtained from locally closed areas as opposed to all possible sources, one sees that far lower consumption frequencies occur with locally caught fish. Since there can be overlap in responses, one person can report

Table 13.

Trends in Consumption Among Consumers of Seafood*

	Prevalence		Enrichment	
	All Fish N = 840	Local Fish N = 145	All Fish N = 110	Local Fish N = 83
	%	%	%	%
Increase	36.4	9.7	42.7	18.1
Same	50.7	27.6	45.5	43.3
Decrease	12.9	62.8	11.8	38.6

* Local fish analyses restricted to participants reporting consumption of two or more local species.

Table 14.

Percent Consuming* Various Species

Fish/Shellfish	Prevalence N = 840 All Fish	 Local Fish	Enrichment N = 110 All Fish	 Local Fish
Clams, quahogs	82.4%	23.3%	99.1%	70.9%
Mussels	20.2	2.0	52.7	19.1
Eel	9.2	1.9	53.6	24.5
Bluefish/Striped Bass/Mackerel	54.3	13.4	90.0	70.0
Scup, tautog, fluke flounder, cod or sea trout	87.3	17.1	100.0	59.1
Lobster	74.4	13.0	96.4	62.7
Catfish, carp, buffalo fish, trout, chub, and drum	14.4	-	40.9	-

* Self reported consumption

consumption of a number of different species. It is notable that only 2% of the population of Greater New Bedford reports eating eels from the closed areas. This species is known to accumulate extremely high body burdens of PCB.

SERUM LEVELS OF PCB AND SEAFOOD CONSUMPTION

A. Quartile Analysis by Type of Consumption.

Information on local seafood consumption, i.e. source, consumption of specific species and frequency of consumption, was displayed by quartile level of PCB to see if any of these responses were more frequent among those persons with higher serum PCB levels. This information is fully described for both males and females in Tables 15 and 16.

No discernible trends in serum PCB level were seen among men or women by source either currently or 10 years ago. Some data cells were quite small, and because overall serum PCB levels were low differences between quartiles were minor, therefore it may not be possible to observe trends. It is noteworthy, however, that among both males and females who report getting no local fish either currently or ten years ago, there does not appear to be a preponderance of lower serum PCB levels.

A number of questions were asked about local lobster, a popular species. The 1979 closure primarily affected this species since it was the only commercial species taken from the inner harbor. It was also a popular sport species. Monitoring programs conducted to measure PCB residue levels in lobster have consistently shown levels which exceed the tolerance of 2.0 ppm first set by the FDA and later adapted by the MDPH.

Table 15.

Questions on Local Seafood by Quartile Prevalence - Males

PCB* Level Range:	Number of Persons Reporting			
	1st 0.5-2.68 n=99	2nd 2.69-3.93 n=97	3rd 3.94-6.84 n=98	4th 6.85-60.92 n=97
OBTAINING LOCAL SEAFOOD - CURRENT				
Catch own	9	8	8	9
Family/friends catch	6	5	4	5
Other local fishermen	1	-	-	-
Local fish retailers	9	12	9	10
Supermarkets	3	5	1	1
Restaurants	4	3	3	1
Get none	62	55	66	66
Don't know	4	10	7	5
OBTAINING LOCAL SEAFOOD - 10 YEARS AGO				
Catch own	13	9	18	13
Family/friends catch	8	10	8	7
Other local fishermen	1	-	-	-
Local fish retailers	12	15	11	11
Supermarkets	1	3	2	-
Restaurants	2	3	1	2
Get none	52	51	53	61
Don't know	9	7	5	3
HAS EATEN LOCALLY TRAPPED LOBSTER				
Five or more times -- yes	13	16	13	9
TIME OF LIFE ATE LOCALLY TRAPPED LOBSTER MOST FREQUENTLY				
Child	2	4	2	2
Teenager	7	6	2	-
Adult	4	6	9	7
FREQUENCY OF EATING LOCAL LOBSTER				
Two or more times/week	1	2	2	1
At least once/week	1	3	2	1
Less than once/week, at least once/month	4	4	4	4
Less than once/month, at least once/year	7	7	5	3
Less than once/year	-	-	-	-

*PCB measured in parts per billion

Page 2
Local Seafood Table
Males (Prevalence) - cont'd.

PCB* Level Range:	1st 0.5-2.68 n=99	2nd 2.69-3.93 n=97	3rd 3.94-6.84 n=98	4th 6.85-60.92 n=97
CONSUMPTION OF LOCALLY TRAPPED LOBSTER				
Increased	1	2	1	1
Same	4	3	3	2
Decreased	8	11	9	6
PARTS OF LOBSTER EATEN				
Claws and tail only	8	9	6	2
Also tomalley	5	7	7	7
SEAFOOD HARVESTED LOCALLY EVER EATEN				
Clams and Quahogs	21	25	33	22
Mussels	4	2	2	1
Eel	2	4	1	4
Blue Fish, Striped Bass or Mackerel	13	14	17	13
Scup, Tautog, Fluke, Cod, or Sea Trout	17	22	17	20

*PCB measured in parts per billion

Table 16.

Questions on Local Seafood by Quartile Prevalence - Females

	Number of Persons Reporting			
	1st	2nd	3rd	4th
PCB* Level Range:	0.38-2.64	2.65-3.90	3.91-6.46	6.47-154.2
	n=113	n=112	n=112	n=112
OBTAINING LOCAL SEAFOOD - CURRENT				
Catch own	4	6	3	7
Family/friends catch	16	9	11	20
Other local fishermen	2	1	3	-
Local fish retailers	14	12	15	11
Supermarkets	4	5	1	1
Restaurants	3	5	1	-
Get none	63	65	73	66
Don't know	7	9	5	7
OBTAINING LOCAL SEAFOOD - 10 YEARS AGO				
Catch own	4	9	3	7
Family/friends catch	15	14	12	23
Other local fishermen	-	1	1	-
Local fish retailers	12	10	12	12
Supermarkets	5	6	4	-
Restaurants	-	4	3	-
Get none	67	56	71	64
Don't know	10	12	6	6
HAS EATEN LOCALLY TRAPPED LOBSTER				
Five or more times -- yes	8	19	21	10
TIME OF LIFE ATE LOCALLY TRAPPED LOBSTER MOST FREQUENTLY				
Child	3	2	3	2
Teenager	1	9	2	-
Adult	4	8	15	8
Don't know	-	-	1	-
FREQUENCY OF EATING LOCAL LOBSTER				
Two or more times/week	1	-	1	-
At least once/week	-	1	5	-
Less than once/week, at least once/month	2	3	9	3
Less than once/month, at least once/year	5	14	6	6
Less than once/year	-	1	-	1

*PCB measured in parts per billion

Page 2
Local Seafood Table
Females (Prevalence) - cont'd.

PCB8 Level Range:	1st 0.38-2.64 n=113	2nd 2.65-3.90 n=112	3rd 3.91-6.46 n=112	4th 6.47-154.2 n=112
CONSUMPTION OF LOCALLY TRAPPED LOBSTER				
Increased	1	2	5	1
Same	1	5	7	4
Decreased	6	12	9	5
PARTS OF LOBSTER EATEN				
Claws and tail only	4	14	10	6
Also tomalley	4	5	11	4
SEAFOOD HARVESTED LOCALLY EVER EATEN				
Clams or Quahogs	20	26	25	24
Mussels	2	1	5	-
Eel	-	1	3	1
Blue Fish, Striped Bass or Mackerel	10	12	18	16
Scup, Tautog, FLuke, Cod, or Sea Trout	11	19	20	18

*PCB measured in parts per billion

Among persons who have eaten locally trapped lobster, there was a generally even distribution throughout the four quartiles for both males and females. It is apparent from the reported frequency of consumption that those who do consume local lobster, do not do so with great frequency. This fact, coupled with small numbers in many of the cells, makes it difficult to see a relationship with serum PCB level. An observation that can be made from this quartile analysis, however, is that persons who reported eating local lobster most frequently as adults were more frequently in the upper quartiles for both men and women. This comment may not be particularly surprising since individuals who consumed lobster most frequently as adults experienced more recent exposure and may also have had a higher consumption rate.

In regard to whether trends in lobster consumption might affect serum PCB level, one can see that although more people reported decreased consumption levels as compared to those who either remained the same or increased their consumption, this fact did not lead to consistent trends toward greater numbers of persons as quartile levels decreased. Likewise, trends toward increasing numbers of persons in increasing quartile serum PCB level among those who reported increased consumption levels were also not noted. The most likely explanation for these findings is that frequency of consumption of local lobster is not high enough to affect serum PCB level.

An interesting issue, which continues to arise in regard to tolerance setting and regulation, is whether or not to consider the tomalley an edible portion of lobster, along with the claw and tail meat. PCBs are found in much higher concentrations in the tomalley. Questions were asked regarding consumption of tomalley and quartile analysis was used to see if

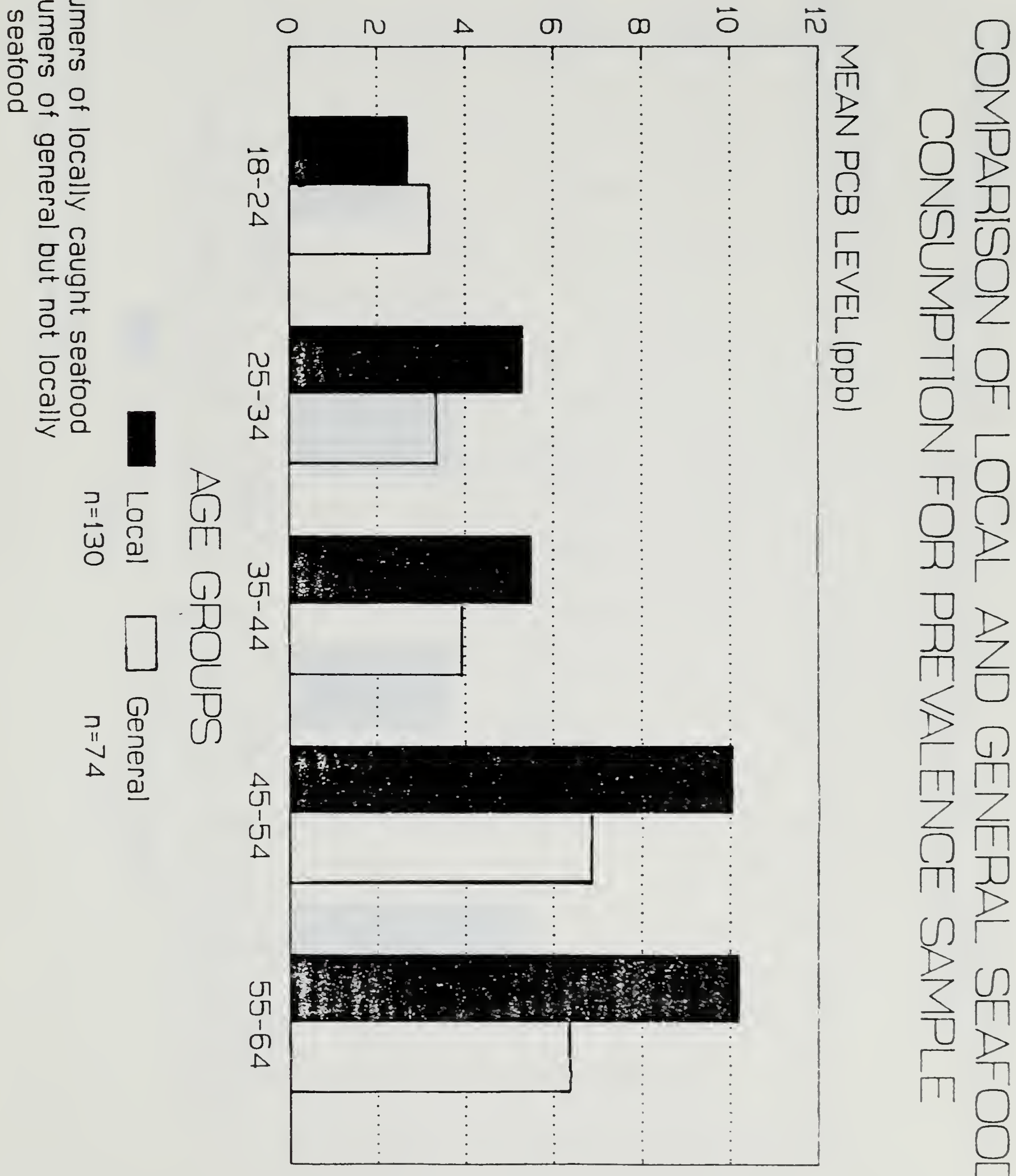
respondents who ate tomalley along with the claws and tail meat might have higher serum PCB levels. Forty-two percent of people who eat lobster also consume the tomalley. However, no trends in level can be seen in this data. In addition to lobster, a number of other locally consumed species, i.e. clams, mussels, eels, blue fish, striped bass, mackerel, scup, tautog, fluke, cod, and sea trout, were also examined in relation to serum PCB level. Females who reported eating bluefish are disproportionately represented in the upper quartile. Again, small numbers in certain categories limit the usefulness of these data.

B. Comparison of Local and General Seafood Consumption.

To address the question of whether local seafood eaters have higher PCB levels than persons who do not consume local species, a comparison was made between these two groups. Mean serum PCB levels were examined within each age group so that age would not confound the findings. Consumers of local seafood have higher mean levels in every age group with the exception of ages 18 through 24 (Figure 10). It is clear from the data that consumers of local seafood are at higher risk of elevated PCB body burdens.

Local seafood consumers were also examined to see whether serum PCB levels increased with increasing frequency of consumption of local species. Slightly higher levels were found among very frequent consumers of local seafood as compared to infrequent consumers (Figure 11). It may be that if frequency of consumption were generally higher among consumers of local seafood in the prevalence population, greater differences in serum PCB level might have been noted.

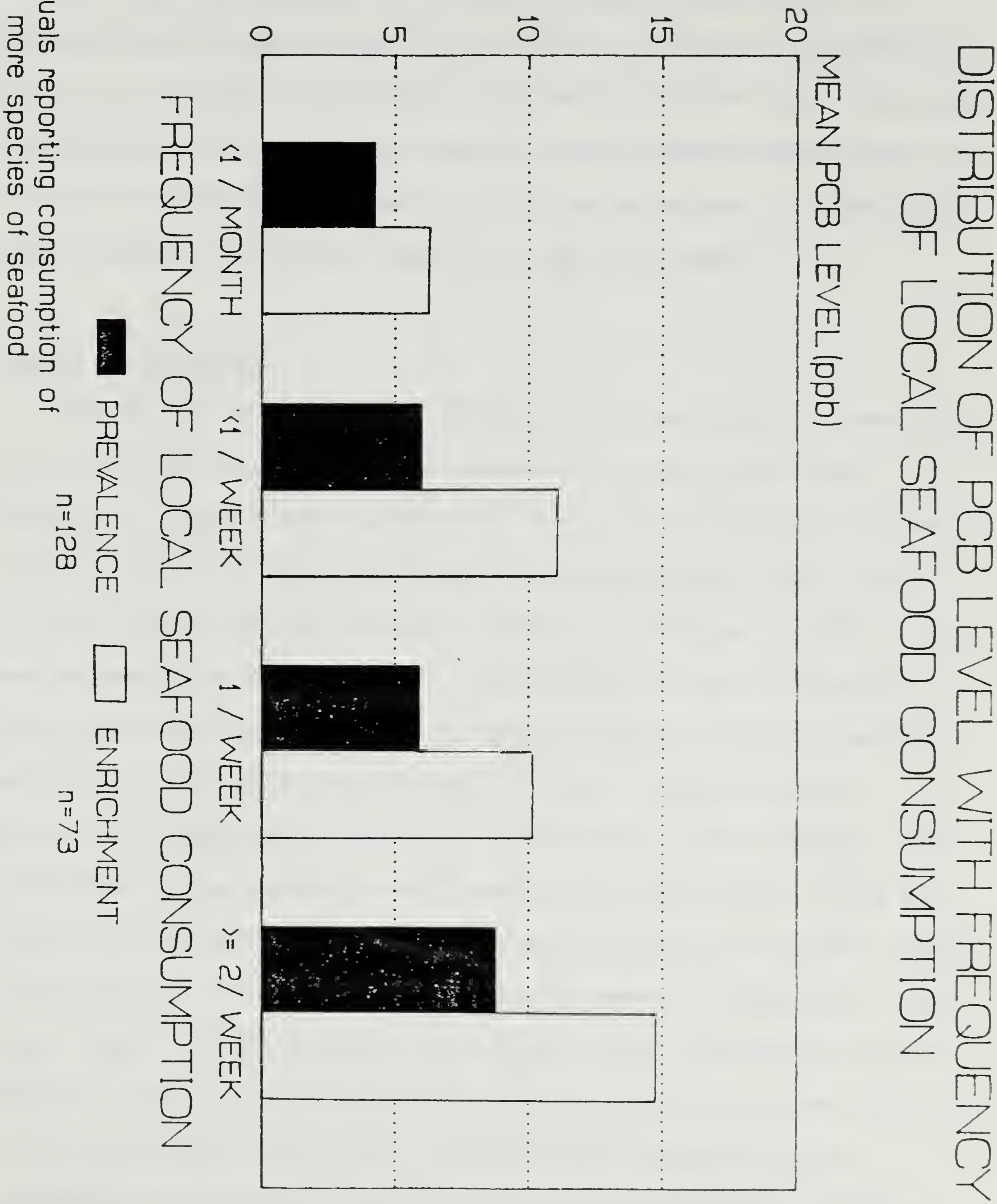
FIGURE 10



COMPARISON OF LOCAL AND GENERAL SEAFOOD CONSUMPTION FOR PREVALENCE SAMPLE

1 consumers of locally caught seafood
2 consumers of general but not locally caught seafood

FIGURE 11



DISTRIBUTION OF PCB LEVEL WITH FREQUENCY OF LOCAL SEAFOOD CONSUMPTION

Individuals reporting consumption of two or more species of seafood

Industrial and Occupational Exposure

Because PCBs were used in a number of manufacturing processes in the New Bedford area over an extended period of time, a large number of questions were included to gather information on occupational history and exposure to materials in which PCBs are known to have been used. Not only were detailed lists of various industries, type of manufacturing employment and specific materials described but these variables were all examined by quartile analysis for males, females, and the total group.

Industry of Employment

The results of the quartile analysis showed many gaps and some cells with very small numbers. However, some categories had high enough frequencies to make a few observations. After males and females had been combined, additional observations could sometimes be made (Table 17). The only category showing increased frequency in the upper quartile is for combined manufacturing industries. This finding is true for males and females separately and combined. An opposite trend is noted for persons employed in construction and the retail trades. Those who report employment in construction tend to be in the lower quartile ranges. This observation is true for both males alone and the total group. It is not possible to draw conclusions regarding females because of the small numbers in these cells. A similar observation can be made with employment in the retail trades. It would appear that for both males and females alone or combined, there is a disproportionate representation in the lower quartiles in the retail trade, not a surprising observation considering the unlikelihood of exposures to PCBs in this type of employment. No other trends could be made regarding frequency of high or low levels by industry

Table 17.

Industry of Employment by Quartile* Prevalence

	Number of Persons Reporting							
	1st		2nd		3rd		4th	
	M	F	M	F	M	F	M	F
n=	98	113	98	112	98	112	97	112
Agriculture, Forestry, Fishery	3	-	4	-	10	-	6	-
Mining	-	-	-	-	-	-	1	-
Construction	18	1	13	-	8	3	9	1
Manufacturing:								
[non-durable goods]	19	27	13	23	19	29	26	43
[durable goods]	13	10	11	6	9	5	21	5
[electrical machinery, equipment, supplies]	-	5	6	7	3	5	4	13
Transportation, Communication, Utilities	5	3	5	3	11	2	7	-
Wholesale trade	1	-	4	2	1	1	2	1
Retail trade	17	31	10	26	9	21	8	9
Finance, Insurance, Real Estate	4	5	-	5	2	5	3	2
Business and Repair services	2	1	6	2	3	4	1	1
Personal services	2	3	2	6	1	5	-	3
Entertainment and Recreational services	1	1	1	2	-	-	-	1
Professional and Related services	8	24	13	22	13	28	5	26
Public Administration	5	-	9	4	7	3	4	4
Not reported	-	2	1	4	2	1	-	3

*PCB Level Range	1st	2nd	3rd	4th
Males	0.5-2.68	2.69-3.93	3.94-6.84	6.85-60.92
Females	0.38-2.64	2.65-3.90	3.91-6.46	6.47-154.2

(PCB measured in parts per billion)

of employment.

Selected Manufacturing Exposures

Again, results of the quartile analysis displayed in Table 18 showed many cells with low frequencies or gaps. Manufacture of hydraulic systems does seem to be reported with greater frequency in the upper quartiles for both males and the total sample. No statements could be made regarding females within this category because of low numbers. Although the numbers are also very small, weak evidence of greater frequency within higher quartiles may also be true for respondents in the manufacture of carbonless copy paper (total group) and for others in the manufacture of vacuum pumps (total group).

Exposure to Specific Materials

After a descriptive quartile analysis for each of the 21 materials which might contain PCBs, it was observed that, despite reasonably good frequencies in most of the cells, most categories of potential exposure did not show discernible trends. The data, displayed in Table 19, would seem to indicate that persons reporting exposure to lubricants (males only) and to rubber (males and total group) were more frequently found in the upper quartiles.

Blood Pressure

Blood pressure measurements (e.g., systolic and diastolic readings) were taken three times during the interview process. *T*-tests performed on systolic and diastolic readings indicated significant differences at the $p = .0001$ level. Therefore, all subsequent statistical analyses were completed with each of the three blood pressure readings.

Table 18.

Selected Manufacturing Exposure by Quartile* Prevalence

Number of Persons Reporting

	1st		2nd		3rd		4th	
	M	F	M	F	M	F	M	F
n =	98	113	98	112	98	112	97	112
CARBONLESS COPY PAPER (manufacture only)	-	1	-	2	1	1	4	1
COATING ELECTRICAL CABLES WITH PLASTIC	4	3	5	3	3	1	4	2
FLOURESCENT LIGHTS (manufacture only)	-	-	-	-	-	-	-	-
GAS TRANSMISSION TURBINES	-	-	-	-	-	-	-	-
HEAT EXCHANGE UNITS OR HEAT TRANSFER SYSTEMS	4	-	2	2	1	2	2	1
HOME AIR CONDITIONERS (manufacture only)	-	-	-	-	-	-	-	2
HYDRAULIC SYSTEMS	8	1	4	-	10	2	13	-
INVESTMENT CASTING IN FOUNDRY	3	-	4	1	4	-	3	1
OLEFIN (manufacture only)	-	-	-	-	-	-	-	-
PAPER RECLAMATION	-	-	1	-	-	-	1	-
T.V. SETS (manufacture only)	-	1	1	-	-	1	-	-
SILK THREAD GLOSSING	-	-	-	3	-	1	-	2
VACUUM PUMPS	3	-	2	-	4	1	9	-

*PCB-Level Range	1st	2nd	3rd	4th
Males:	0.5-2.68	2.69-3.93	3.94-6.84	6.85-60.92
Females:	0.38-2.64	2.65-3.90	3.91-6.46	6.47-154.2

(PCB measured in parts per billion)

Table 19.
Material Exposure by Quartile*
Prevalence

	Number of Persons Reporting							
	1st		2nd		3rd		4th	
	M	F	M	F	M	F	M	F
n =	98	113	98	112	98	112	97	112
Adhesives	19	16	22	15	24	14	22	11
Compressor fluids	14	2	18	7	18	1	13	4
Caulking compounds	25	2	27	4	24	3	16	3
Cutting oils	20	5	32	8	26	4	37	10
Dedusting agents	10	3	11	7	9	1	9	2
Dyes	15	9	20	13	17	11	21	9
Flame retardants	10	7	11	10	14	6	9	2
Herbicides	5	-	7	1	7	2	4	-
Hydraulic fluids	27	3	32	7	39	3	34	1
Immersion oil	2	1	4	1	3	1	3	2
Lacquers	21	5	24	15	26	6	27	6
Lubricants	31	15	38	17	43	13	49	20
Paints	47	11	42	16	35	3	41	12
Plasticizers	9	-	10	8	14	3	9	1
Putty	27	1	27	2	20	-	17	1
Resins	15	3	19	4	21	7	18	7
Rubber	21	6	17	14	25	11	32	18
Sealants	20	5	23	10	20	3	18	5
Varnishes	20	6	22	6	22	2	14	2
Wax extenders	5	2	4	5	7	1	1	1
Wood preservatives	19	1	15	3	15	1	13	-

*PCB Level Range - Males 0.5-2.68 2.69-3.93 3.94-6.84 6.85-60.92
Females 0.38-2.64 2.65-3.90 3.91-6.46 6.47-154.2
(PCB measured in parts per billion)

The mean systolic readings and standard deviations for the prevalence sample ($\underline{n}$ = 840) were 115.26 ±18.85, 113.69 ±17.62, and 114.28 ±11.41. The mean diastolic readings for the prevalence sample were 72.19 ±10.94, and 73.19 ±10.95, and 73.17 ±10.94, respectively. Systolic and diastolic values ranged from 69.00 to 228.00 and from 36.00 to 120.00. When the prevalence sample was examined by sex, there was no significant difference in systolic and diastolic blood pressure readings.

Pearson $\underline{r}$ correlations of specific independent variables were performed to help identify patterns and trends. These variables included serum PCB level, age, body mass, and systolic and diastolic readings. Age was moderately correlated with PCB level for all systolic and diastolic blood pressures. The correlations ranged from .33 to .51 ($\underline{p}$ = .0001). There was no relationship found between body mass and age. When the prevalence sample was examined by sex the same relationships were noted. In addition, there were significant moderate correlations for females ($\underline{n}$ = 449) and males ($\underline{n}$ = 391) between age and PCB levels ($\underline{r}$ = .30, $\underline{r}$ = .39, $\underline{p}$ = .0001). (Appendix II)

Therefore, it was apparent that the prevalence sample did not demonstrate significant patterns among the correlations of independent variables found to be predictive of serum PCB levels from the literature. The exception was the observed relationship of age and serum PCB level; however, age did not predict serum PCB level when regression models were used. Multivariate models using multiple regression and log linear models were attempted. None proved to be significant when using age, body mass, and systolic and diastolic blood pressure readings as the independent variables predicting serum PCB levels. In addition, age, body mass, and PCB level were used as independent variables with systolic and diastolic

blood pressure readings as the dependent variables. Again, no significant models were found. This result was not surprising, based on the lack of significant patterns found among the correlations.

Refusers

Of the 635 individuals who refused to participate, 560 (89.0%) completed the refusal questionnaire. Review of these data show the refusers and participant populations to be similar with regard to employment at a capacitor manufacturing firm. Of the refusers who completed the refusal questionnaire 17.9% (n = 102) reported past or present employment at one of the two local capacitor manufacturers, as compared to 21.1% (n = 177) of the prevalence study participants. Since there are no data on work history of refusers in the capacitor industry, it is impossible to compare duration of employment or specific occupation.

Limited data are available for comparing seafood consumption between the two populations. The survey instrument administered to actual study participants was quite detailed in this regard and provided extensive information on types of seafood consumed, seafood sources, and frequency of consumption for both general and local (contaminated) seafood. For the refusal questionnaire these questions were condensed into two: 1) "Do you eat a lot of fish and/or lobster (3X or more/week)?"; and in the event of a positive answer, the followup question, 2) "Where do you get your fish and lobster?". Given the differences in survey instruments, it is difficult to assess whether the two populations have an equal possibility of ingesting contaminated seafood. It is possible, however to offer a fair characterization of general seafood consumption habits among the refusers.

There were 101 (17.9%) refusers who reported eating "a lot" of fish and lobster. Of the participants, 128 (15.2%) reported eating seafood two or more times per week. Refusers were also asked how they obtained their local seafood. (It is important to note that this group of individuals were not offered a choice of responses [i.e., catch own, family/friends, etc.] but rather, self-reported their source of seafood.) Only 9.8% of the refusers reported "catch own" or "family/friends" as their means of obtaining locally caught seafood, compared to 25% of participants. This number may lend credence to an assumption that consumers of potentially contaminated seafood were not underrepresented in this investigation.

Medical conditions were also covered extensively in the survey instrument. The refusal questionnaire contained one question designed to pinpoint any chronic, recurring medical conditions. No association was found between the presence of medical conditions and refusal to participate. This supports the assumption that illness was not a deterrent to participation in the study.

Chi square tests were performed for association of refusal to participate and age, sex and residence. Occupational data other than employment in an electrical manufacturing plant was obtained largely from the local census. Therefore it was not included for comparison here. Age was significantly associated ($x^2 = 11.865$ with 4 d.f., $p = .018$) with refusal for females. This association was not significant among males who refused to participate. Neither sex nor city/town of residence was associated with refusal in both male and female subgroups.

A list of reasons individuals gave for refusing are listed in Appendix FF. The three predominant responses are: 1) no time (26.3%); 2) not interested (14.5%); and 3) no clear reason given (23.6%).

ENRICHMENT

As a result of the low serum PCB levels observed in the preliminary findings (n = 322) of the Phase I Prevalence Study, it became apparent that an exposed group of individuals (i.e. 150 people) would not be identified by random selection. On the basis of these findings, the MDPH and the CDC decided to conduct an enrichment study. Enrichment participants consisted of residents identified as being at greater risk of exposure to PCBs because of frequent intake of contaminated seafood.

The goal of the Enrichment Study was to identify the group of 150 individuals necessary for proceeding to Phase II of the GNBHES.

Enrichment Serum PCB Distribution: The distribution of levels among participants of the Enrichment Study are presented in Table 20. The range in levels for this sample was 1.40 ppb to 87.97 ppb with a median of 9.48 ppb and a mean of 13.34 ppb.

Enrichment PCB Level by Reported Ethnicity: Table 21 presents the distribution of serum PCB levels among Portuguese/Cape Verdean in comparison to non-Portuguese/Cape Verdean enrichment study participants. As was observed in the prevalence sample, participants reporting their ethnicity as either Portuguese or Cape Verdean had slightly higher mean serum PCB levels (17.1 ppb vs. 11.4 ppb).

Enrichment Serum PCB Level and Age: Figure 12 shows the relationship of serum PCB level to age among the enrichment study participants (n=110). In the three age groups into which enrichment participants were categorized

Table 20.

Distribution of Serum PCB Levels
Enrichment

	MALES n=89		FEMALES n=21		TOTAL n=110	
Serum PCB Level*	n	%	n	%	n	%
0.0 - 1.49	-	-	1	4.8	1	.9
1.5 - 2.99	-	-	2	9.5	2	1.8
3.0 - 4.49	14	15.7	2	9.5	16	14.6
4.5 - 5.99	12	13.5	-	-	12	10.9
6.0 - 7.49	14	15.7	1	4.8	15	13.6
7.5 - 8.99	6	6.7	1	4.8	7	6.4
9.0 - 10.49	6	6.7	2	9.5	8	7.3
10.5 - 11.99	5	5.6	4	19.1	9	8.2
12.0 - 13.49	6	6.7	-	-	6	5.5
13.5 - 14.99	2	2.3	1	4.8	3	2.7
15.0 - 16.49	5	5.6	1	4.8	6	5.5
16.5 - 17.99	3	3.4	1	4.8	4	3.6
18.0 - 19.49	1	1.1	1	4.8	2	1.8
19.5 - 20.99	2	2.3	1	4.8	3	2.7
21.0 - 22.49	2	2.3	-	-	2	1.8
22.5 - 23.99	2	2.3	1	4.8	3	2.7
24.0 - 25.49	1	1.1	-	-	1	.9
25.5 - 26.99	2	2.3	-	-	2	1.8
27.0 - 28.49	1	1.1	-	-	1	.9
28.5 - 29.99	-	-	-	-	-	-
30.0 +	5	5.6	2	9.5	7	6.4
NEXT TO HIGHEST		63.76		55.70		83.99
HIGHEST		87.97		83.99		87.97
MEAN		12.63		16.34		13.34
MEDIAN		8.46		10.74		9.48
STANDARD DEVIATION		12.48		19.33		14.02
25TH PERCENTILE		5.57		5.39		5.59
75TH PERCENTILE		15.79		17.58		15.93

*PCB measured in parts per billion

Table 21.

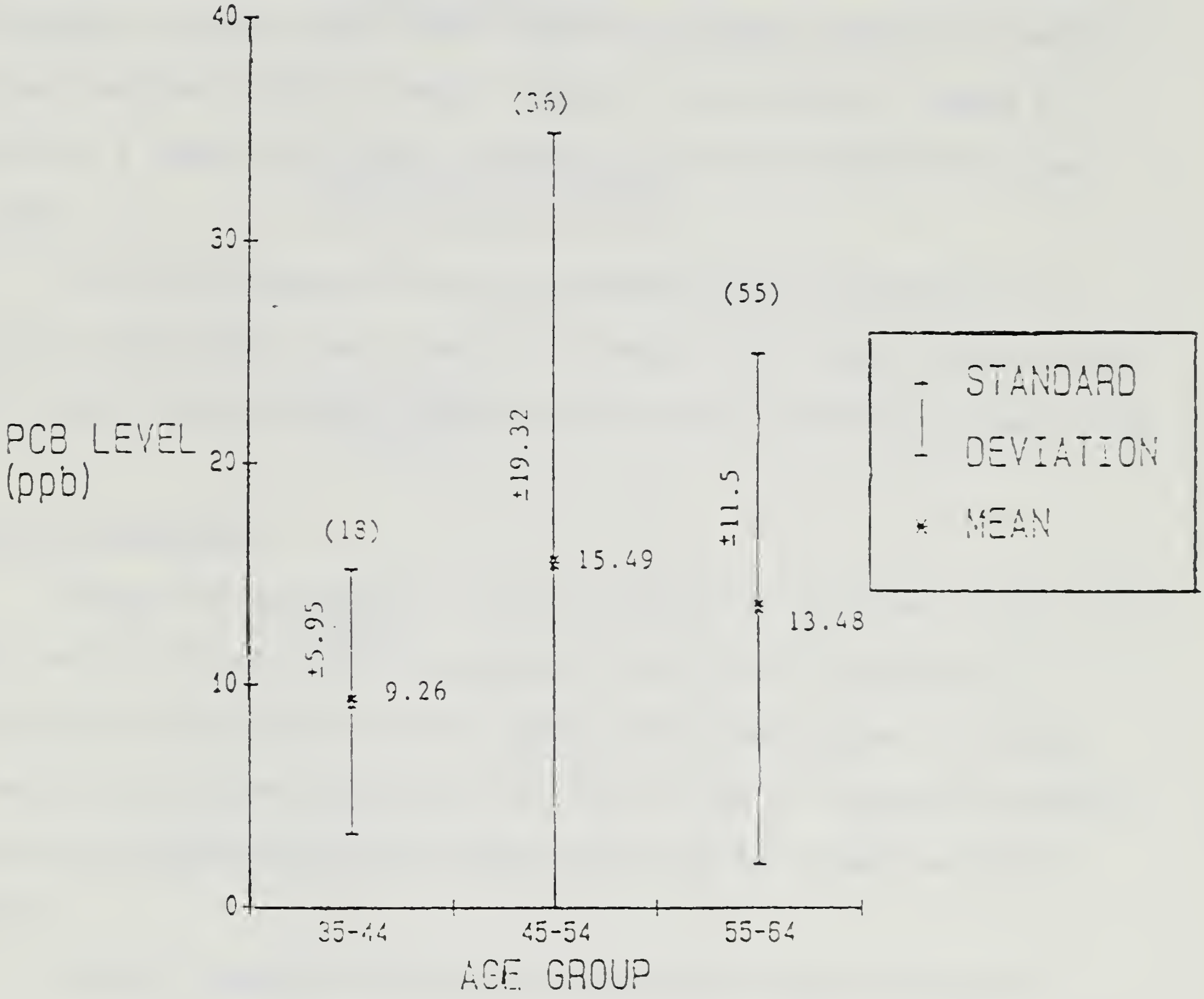
Serum PCB Level Distribution among Portuguese and Cape Verdean as Compared to All Others

Enrichment Participants

	Portuguese		Non-Portuguese	
LEVEL	N (N=37)	% OF TOTAL	N (N=73)	% OF TOTAL
0 - 1.49	1	2.7	-	-
1.5 - 2.99	-	-	2	2.7
3.0 - 4.49	1	2.7	15	20.6
4.5 - 5.99	3	8.1	9	12.3
6.0 - 7.49	6	16.2	9	12.3
7.5 - 8.99	2	5.4	5	6.9
9.0 - 10.49	2	5.4	6	8.2
10.5 - 11.99	2	5.4	7	9.6
12.0 - 13.49	3	8.1	3	4.1
13.5 - 14.99	1	2.7	2	2.7
15.0 - 16.49	4	10.8	2	2.7
16.5 - 17.99	1	2.7	3	4.1
18.0 - 19.49	-	-	2	2.7
19.5 - 20.99	2	5.4	1	1.4
21.0 - 22.49	1	2.7	1	1.4
22.5 - 23.99	2	5.4	1	1.4
24.0 - 25.49	-	-	1	1.4
25.5 - 26.99	1	2.7	1	1.4
27.0 - 28.49	1	2.7	-	-
28.5 - 29.99	-	-	-	-
30.0 +	4	10.8	3	4.1
NEXT TO HIGHEST		55.70		63.76
HIGHEST		87.97		83.99
MEAN		17.14		11.41
MEDIAN		13.38		8.38
STANDARD DEVIATION		16.21		12.45
25TH PERCENTILE		7.00		4.64
75TH PERCENTILE		20.74		13.46

FIGURE 12

MEAN and STANDARD DEVIATION
SERUM PCB LEVEL[1] by AGE GROUP
ENRICHMENT



note: One participant was eliminated because they fell outside of these age groups.

[1] PCB measured in parts per billion

(i.e., 35-44, 45-54, 55-64) the mean serum PCB levels were: 9.26, 15.49, 13.48 ppb respectively.

Serum PCB Level range - Prevalence vs. Enrichment

To better assess the comparison of serum PCB levels of the randomly selected sample (i.e. prevalence) to the enrichment sample, the GNBHES programmer, using a random number generator program, selected a control group from the Prevalence Sample matched on age and sex. Figure 13 presents a comparison of the distribution of levels between these two groups.

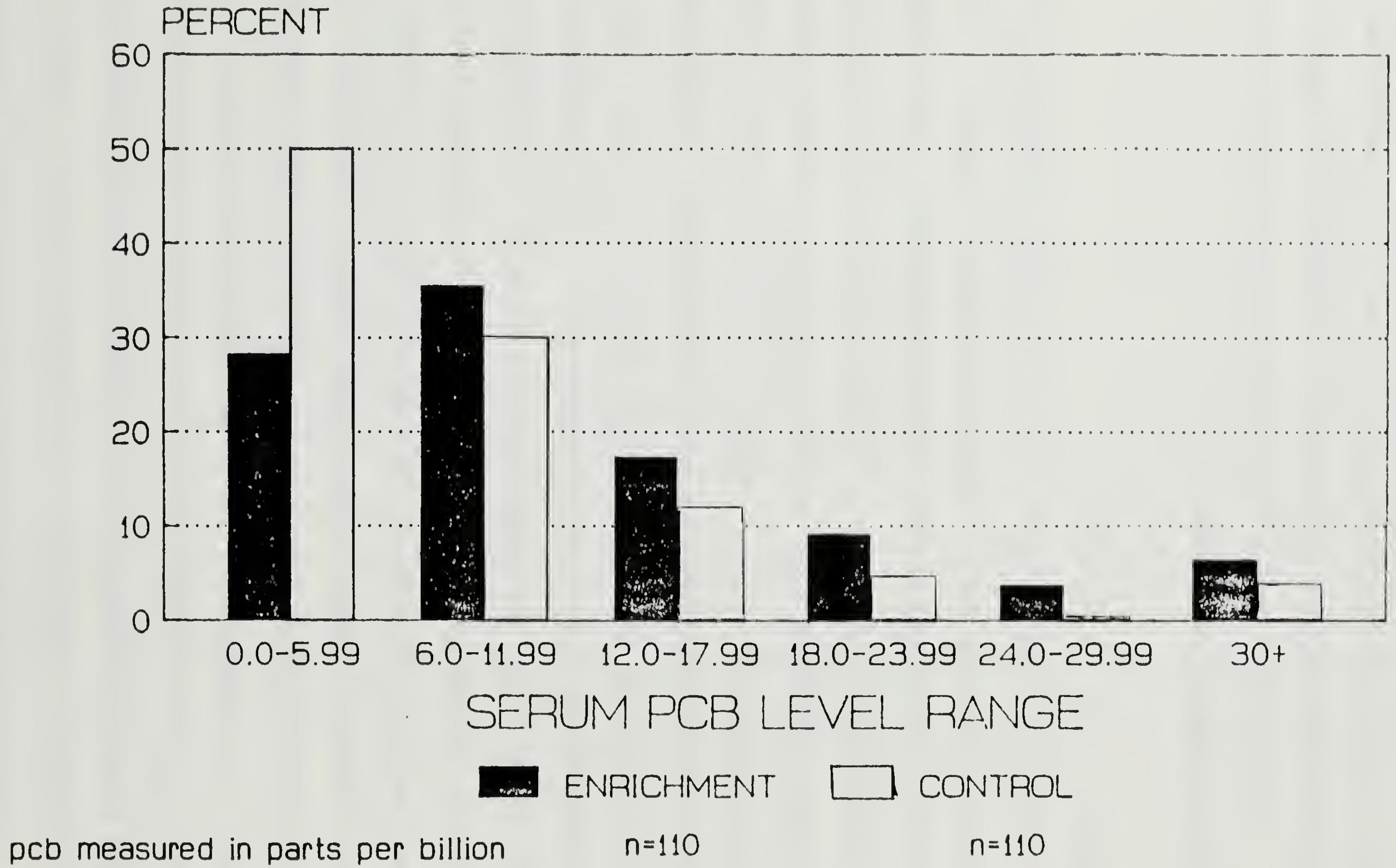
It is not unexpected that the enrichment group (individuals at greater risk) shows greater numbers of people in the upper range of serum PCB levels because of the criteria set for entry into the Enrichment Study.

Seafood Consumption

Because the prevalence of elevated serum PCB levels was found to be low, and the frequency of consumption of local fish from areas of substantial PCB pollution was low among participants chosen by random sample, the enrichment group was recruited to see if more people could be found who consumed PCB contaminated species and had higher serum PCB levels.

Overall, marked differences in response to seafood consumption questions were noted between the enrichment and prevalence populations. Male and female responses were grouped for the analysis of enrichment data since these groups were small and did not show appreciable differences when results were examined separately.

FIGURE 13



FREQUENCY DISTRIBUTION TABLE COMPARING ENRICHMENT WITH PREVALENCE CONTROLS

Seafood Source

The most frequently mentioned source from which people currently obtain seafood is from local fish retailers (Table 9). Fifty-four percent of the prevalence and 41% of the enrichment sample cited this source. The major difference regarding the source of seafood between the two study groups is the percentage of respondents who reported catching their own. Thirty-five percent of the enrichment population report catching their own fish as compared with only 4.2% in the prevalence population. This finding is not unexpected in light of the method by which the enrichment sample was selected. In looking to see whether the primary seafood source had changed since 10 years ago, one finds that the same sources are named by approximately the same relative percentages. Similar patterns are observed for local seafood consumption (Table 11 and 12). Again, the most important contrast between the two study populations is among those who report obtaining no seafood. Among those persons in the enrichment group who report getting no local seafood, one does see a drop of eight percentage points over the last 10 years, which may be an indication that the local fishing prohibitions have had some effect. It is, however, quite clear from Tables 11 and 12 that the enrichment population is more exposed to contaminated local seafood than is the Greater New Bedford population in general.

Trends in Seafood Consumption

The enrichment sample participants as well as those in the prevalence sample were asked whether their general consumption of seafood as well as locally caught seafood had increased, decreased or remained about the same over the last 10 years (Table 13). The overwhelming response in both

sample populations indicated that a very high percentage (85-89%) either increased this general consumption or it remained the same. Conversely, only a very small percentage of both groups reported a decrease. Among the persons in the enrichment sample who consumed at least two different species of local seafood, a much higher percentage reported a decrease. This decrease was substantially higher than that reported for general seafood consumption. This finding is again consistent with the fishing prohibitions. A decrease (61%) in consumption of local seafood is also seen in the prevalence population among those who report consumption of two or more local species. However, only about 20% of the prevalence group reports eating these local species, whereas approximately 75% of the enrichment sample does.

An even more important observation regarding trends among persons who report local seafood consumption might be that despite widespread public education regarding the local PCB contamination problems, 61.4% of the enrichment sample and 36.3% of prevalence sample indicated that their level of local consumption had either increased or been maintained. This finding would seem to indicate a need for both better enforcement activities and environmental health educational programs geared to recreational fishermen.

Preferred Species of Consumption

A list of specific species of fish was given to respondents of both enrichment and prevalence groups to ascertain the percentage of each group that consumed each species both in general and from defined local areas. Some species have been found to contain elevated levels of PCBs regardless of their source (30). Others are known to have been elevated if taken from contaminated areas.

In examining the percentage of respondents in both the enrichment and prevalence samples who report eating each different species, it is quite apparent that a greater percentage of the enrichment sample consumes every species than does the prevalence group (Table 14 and 22). This is true for both general seafood consumption and for seafood obtained from local areas. Some species, such as clams, scup, tautog, fluke, flounder, cod, sea trout, lobster, are clearly more popular than others, such as mussels, eels, and fresh water species. Responses show markedly higher percentage consumption of species in which PCBs are routinely found among the enrichment than among the prevalence population. For this reason, further analysis was done to see if consumption of these species was more frequently reported among respondents with upper PCB quartile levels than in lower ones.

ENRICHMENT SERUM LEVELS OF PCB AND SEAFOOD CONSUMPTION

A. Patterns by Quartile

Patterns in local seafood consumption were examined by serum PCB level quartile to see whether any responses were more frequently reported in higher quartiles (Table 22). Specific types of seafood consumption, trends in local lobster consumption, and catching one's own seafood both now and 10 years ago were analyzed for the presence of trends by serum PCB level quartile. No obvious differences in frequencies were seen for specific species consumed; for individuals who currently or formerly trapped their own local lobster; for either increasing or decreasing trends in consumption; or for consumption of various edible portions of lobster. It is interesting to note that 56% of respondents who reported consuming locally trapped lobster consumed the tomalley.

Table 22.

Local Fish Consumption Patterns by Quartile

Enrichment

PCB Level Range*	1st 1.4-5.61 n = 28	2nd 5.62-9.48 n = 27	3rd 9.49-15.7 n = 27	4th 15.71-87.97 n = 28
	Number of Persons Reporting			
SPECIES CONSUMED				
Clams, quahogs	20	18	22	18
Mussels	7	1	9	4
Eels	5	5	7	10
Bluefish, striped bass and/or mackerel	17	18	24	18
Scup, tautog, fluke, flounder, cod, and/or sea trout	18	14	21	12
Lobster	19	13	21	16
PARTS LOBSTER				
Claws and tail	8	7	9	6
Also tomalley	11	6	12	10
PRIMARY SOURCE AS CATCH OWN FISH				
Now	14	12	19	13
Ten years ago	13	15	22	19
TRENDS IN LOCAL LOBSTER CONSUMPTION				
Increased or same	14	8	13	7
Decreased	5	5	8	9

*PCB measured in parts per billion

B. Frequency of Local and General Seafood Comparisons

Answers to the question of whether persons who report greater frequency of consumption of local species have higher serum PCB levels are presented in Figure 11. In the enrichment group, serum PCB levels increase with increasing frequency of consumption. This result is consistent with that seen for prevalence, only it is more pronounced in the enrichment sample.

Industrial and Occupational Exposure

Information on both industry of employment and specific occupation was collected. As in the prevalence group, occupational information reported was so widely scattered that few persons fell into any one category to be useful for in-depth analysis. Industry of employment, specific manufacturing employment and material exposures were analyzed descriptively by quartile frequency distributions by serum PCB levels. A quartile analysis approach was chosen to indicate whether persons with the highest serum PCB levels were disproportionately represented in certain types of industries, and, if so, whether those industries were likely to pose occupational exposure to PCBs. As in other enrichment analyses, males and females were grouped because of the small size of the groups.

Industry of Employment

Reported industries of employment were widely and rather evenly distributed among the enrichment population (Table 23). An examination of the quartile analysis showed no trends or clustering of persons with higher serum PCB levels by industry of employment, with the possible exception of the manufacture of electrical machinery and supplies. Persons reporting

Table 23.

Industry of Employment by Quartile

Enrichment

PCB* Level Range	Number of Persons Reporting 1st 1.4-5.61 n = 28	2nd 5.62-9.48 n = 27	3rd 9.49-15.7 n = 27	4th 15.71-87.97 n = 28
Agriculture, Forestry, Fishery	2	0	1	2
Construction	4	2	4	4
Manufacturing:				
A. Non-Durable Goods	4	5	3	1
B. Durable Goods	3	2	3	3
C. Electrical machinery, equipment, supplies	0	1	3	7
Transportation, Communication, Utilities	2	3	0	5
Wholesale Trade	0	1	0	1
Retail Trade	5	2	3	1
Finance, Insurance, Real Estate	0	1	1	0
Business Repair Services	0	1	2	1
Professional & Related Services	7	4	4	0
Public Administration	1	5	3	3

*PCB measured in parts per billion

employment in this industry were more frequently found in the upper two quartiles. This result is not unexpected when one considers the history of electrical capacitor manufacturing in New Bedford and the extensive, long term use of PCBs within that industry. It should also be noted that for workers reporting employment in the professional service category a disproportionate number seemed to be represented in the lower quartile ranges. A weak trend in this same direction might be also true for individuals in retail trade.

Selected Manufacturing Exposures

A number of specific manufacturing processes have been reported to present potential exposure to PCBs. Information on these processes was sought from respondents, and quartile levels were determined to show frequency in relation to the information. Data were examined to see whether persons in upper quartiles were more likely to report employment in these manufacturing categories. Results indicate that numbers in each category were so small that it was not possible to observe any trends (Table 24).

Exposure to Specific Materials

Another possible source of PCBs might be contact either through the use or manufacture of various types of materials that contain these compounds. It is well known that PCBs, because of their chemical and physical properties, found widespread application in a variety of products. For this reason, information was collected on contact with materials thought to potentially contain PCBs either now or in the past. One can see that many of these materials are frequently mentioned by the enrichment

Table 24.

Selected Manufacturing Exposure by Quartile

Enrichment

	Number of Persons Reporting			
	1st	2nd	3rd	4th
PCB* Level Range:	1.4-5.61	5.62-9.48	9.49-15.7	15.71-87.97
	n =28	n = 27	n = 27	n = 28
CARBONLESS COPY PAPER (manufacture only)	0	0	0	0
COATING ELECTRICAL CABLES WITH PLASTIC	3	2	3	1
FLOURESCENT LIGHTS (manufacture only)	1	0	0	1
GAS TRANSMISSION TURBINES	0	0	0	0
HEAT EXCHANGE UNITS OR HEAT TRANSFER SYSTEMS	2	0	0	1
HOME AIR CONDITIONERS (manufacture only)	0	1	0	1
HYDRAULIC SYSTEMS	4	3	3	2
INVESTMENT CASTING IN FOUNDRY	0	2	1	0
OLEFIN (manufacture only)	0	0	0	0
PAPER RECLAMATION	1	0	0	0
T.V. SETS (manufacture only)	0	1	0	0
SILK THREAD GLOSSING	0	0	0	0
VACUUM PUMPS	3	0	1	1

*PCB measured in parts per billion

respondents (Table 25). Clearly, not all products within each category contains PCBs; therefore, simply reporting exposure to a particular material or group of materials is not synonomous with exposure to PCBs. However, since a percentage of materials within each material category contains PCBs, contact does increase the risk of exposure. Therefore, data were examined for a number of persons within each quartile who reported contact with each specific material, to see if certain types of exposures were disproportionately represented by persons having higher levels of PCBs. Certain material exposures did appear to be more frequently reported among higher quartiles such as exposures to putty, sealants, varnishes, and wood preservatives.

Blood Pressure

Blood pressure was also analyzed in the enrichment sample ($\underline{n}$ = 110). The first, second and third mean systolic readings were 128.45 ±15.58, 124.69 ±16.11, and 125.66 ±16.55 (range = 96.00 - 186.00). The mean diastolic readings were 83.47 ±9.43, 80.86 ±9.74, and 81.16 ±10.54 (range = 52.00 - 128.00). Correlations of systolic and diastolic readings, age, body mass, and serum PCB levels revealed no significant relationships among variables except for the second systolic blood pressure reading and PCB level ($\underline{r}$ = .53, $\underline{p}$ = .01) in females. However, there were also significant associations between the second and third systolic blood pressure readings and age ($\underline{r}$ = .55, $\underline{p}$ = .01; $\underline{r}$ = .46, $\underline{p}$ = .04). Because of the small sample size, these correlations are difficult to interpret. There may, in fact, be no relationship between serum PCB level and systolic blood pressure since the age variable may be confounding the interpretation of these

Table 25.
Materials Exposure by Quartile Enrichment

	Number of Persons Reporting			
	1st	2nd	3rd	4th
PCB* Level Range:	1.4-5.61	5.62-9.48	9.49-15.7	15.71-87.97
	n = 28	n = 27	n = 27	n = 28
ADHESIVES	8	5	8	9
COMPRESSOR FLUIDS	8	8	3	5
CAULKING COMPOUNDS	7	5	11	10
CUTTING OILS	11	12	14	15
DEDUSTING AGENTS	2	2	4	3
DYES	8	6	6	8
FLAME RETARDANTS	2	4	1	2
HERBICIDES	2	1	1	4
HYDRAULIC FLUIDS	11	9	7	14
IMMERSION OIL	1	2	0	1
LACQUERS	8	4	10	8
LUBRICANTS	13	13	11	16
PAINTS	11	12	15	14
PLASTICIZERS	3	5	2	4
PUTTY	3	5	8	12
RESINS	10	9	7	13
RUBBER	12	8	10	11
SEALANTS	5	4	8	12
VARNISHES	4	3	8	9
WAX EXTENDERS	1	3	1	4
WOOD PRESERVATIVES	2	3	8	8

*PCB measured in parts per billion

variables. Multivariate models were not applied because of the size of the sample.

HEAVY METALS IN THE GREATER NEW BEDFORD POPULATION

Results of studies of sediments from the Acushnet River estuary and landfills in and around Greater New Bedford, Massachusetts, performed before the planning and design of the Greater New Bedford Health Effects Study, showed evidence of significant heavy metal contamination (31). Some of the known toxic effects from heavy metal exposure resemble the reported health effects of polychlorinated biphenyl (PCB) exposure. The health effects of exposure to inorganic lead, inorganic mercury, organic mercury, and the various inorganic and organic species of arsenic are summarized here. Inorganic arsenic can cause peripheral neuritis, myelitis, or motor paralysis. In contrast, arsenic in its dietary forms can be tolerated in humans without toxic effects even at relatively high levels. Inorganic lead causes encephalopathy and central nervous system damage and is positively correlated to blood pressure (32). Mercury is neurotoxic in both its inorganic and organic forms, with the organic moieties (e.g., methylmercury) having considerably greater toxicity (33).

The study design therefore included plans to measure these metals in a 10% subset of study participants. The findings could then be used to determine: 1) if a public health problem with regard to human exposure to these heavy metals existed in the Greater New Bedford community, and 2) if the effects of exposure to these metals produced a potentially confounding source of symptoms which might be interpreted as symptoms due to PCB exposure. Measurements in biological fluids could serve as markers for

undue absorption of these toxicants. This study chose to measure urine arsenic, urine mercury and blood lead on the basis of the known distribution and excretion patterns of these metals.

As the study progressed, it was decided to include measurements of speciated arsenic in any specimens with elevated total urinary arsenic, to clarify the presumed dietary origin of any elevated levels observed. Although urinary inorganic mercury is the analyte of choice for overall mercury exposure, the presence of alkylated forms of mercury, which might also be absorbed from dietary sources, was assessed by total mercury analyses on whole blood. Analyses were done on persons from the prevalence study with elevated urinary arsenic and on a small number of arbitrarily chosen specimens. Findings with regard to exposure to these heavy metals are described in detail in Appendix BB and are summarized here.

Urine and whole blood specimens from a 10% subset of respondents in the Prevalence and Enrichment components of this study were examined for concentrations of blood lead, urinary total arsenic and urinary inorganic mercury. This subset consisted of 106 persons -- 96 persons from the Prevalence group and 10 persons from the Enrichment group. Ten samples from the total subset with urinary total arsenic >100 ng/mL were also tested fro arsenic speciation to determine the dietary (nontoxic) contribution to these elevations. In addition, 48 blood specimens from respondents were also tested for blood total mercury.

Results of this study of heavy metal exposure in residents of the Greater New Bedford area showed no evidence of excessive exposure to toxic forms of any of the elements tested. Levels of blood lead were within the expected range for nonoccupationally exposed adults and are typical of levels observed in urban adults in the United States. The urinary

inorganic mercury and blood total mercury levels measured were well below published exposure limits. This supports the conclusion that excessive exposure to elemental and organic forms of mercury did not occur in the persons tested. Total and speciated urinary arsenic measurements demonstrated that the only obvious exposure to arsenic was in the form of the relatively nontoxic dietary form of arsenic (predominately from seafood), and levels were well below action levels for this form of arsenic.

Elevated levels of certain heavy metals have been demonstrated in sediments from the Acushnet estuary and samples from local landfills and other sites; furthermore, the potential for industrial exposure is present among workers in the community. Results of this study of 106 New Bedford area residents, however, showed no evidence of excessive human exposure to lead, arsenic, or mercury in the community.

CHAPTER IV

DISCUSSION

After final disposition of all randomly selected participants of the Greater New Bedford Health Effects Study a response rate of 57% (Table 2) was observed in the prevalence sample. Although this figure may be considered low in comparison to clinical trials of a similar nature, discussions with scientists involved in investigations throughout the United States have indicated a decline in overall response rates. Some investigators are now compensating participants with hopes of achieving a response rate of 50% (35). In all cases it is necessary to obtain a sample with sufficient statistical power in order to draw meaningful conclusions from data collected. In the case of a prevalence study (like the GNBHES), it is of utmost importance that a representative sample is gained since we are making statements descriptive of a large population based on a statistical sample of the population. The GNBHES staff were able to meet original sample size estimates that enabled a test to be performed for a doubling of the expected prevalence of elevated serum PCB levels with a power of 80%.

It is clear from the data presented in Table 5 and Figure 8 that the prevalence of elevated serum PCB level among residents of Greater New Bedford is low. This observation remains true for both male and female subgroups as well as the total prevalence study group. This event was not expected due to the high level of contamination that still exists in and around New Bedford harbor and the Acushnet River Estuary. For the most part, even the Greater New Bedford residents with highest risk of exposure from diet or occupation had serum PCB levels well within the range of CDC

from diet or occupation had serum PCB levels well within the range of CDC estimates on a national basis for non-exposed U.S. residents that participated in other studies (1% $\geq$ 30 ppb).

It is also evident that residents of individual cities and towns within the study area (New Bedford, Acushnet, Dartmouth, and Fairhaven) do not differ greatly in regard to PCB serum levels and that no greater risk of exposure to PCBs exists in any one of the four cities and towns.

The data have shown (Figure 9) that the age of an individual is correlated with serum PCB level. A relationship between age and serum PCB level was observed among participants of the prevalence study. As data for each ascending prevalence age group was reviewed, the mean PCB levels increased proportionally among the five age intervals. It should be noted that although the relationship of age to serum PCB level was significantly correlated, age did not predict PCB level in the regression model. This relationship (age and serum PCB level) was supported in studies conducted by Kriess et al in 1982 (14) among farmers from Michigan.

In addition to this relationship, it is also noteworthy that in the general distribution of serum PCB levels, among those residents who reported having a Portuguese or Cape Verdean ethnicity, there exists a slightly higher mean PCB serum level. This observation held true for the total prevalence group and proportionally in each of the five age groups examined in this sample. After controlling for occupational and seafood consumption confounders as well as variability in laboratory analyses, this difference in levels diminished among ethnic groups.

The distribution of serum PCB levels among residents participating in the enrichment study (Table 20) show a higher mean and median level for this group of individuals. This finding was expected since this group was

recruited to participate largely on the basis of known seafood consumption exposures as well as an age confinement and a small number of people with previous known occupational exposures. It remains of interest that the utilization of the screening questionnaire enabled study staff to identify individuals with higher serum PCB levels due to a determination that these individuals were truly at higher risk of exposure to PCBs. The data collected in the enrichment study contribute greatly to more accurate assessments of exposure to PCBs among a high risk population. The mean serum PCB level for this group was 13.34 ppb which is almost three times greater than that of the prevalence (i.e. general population) group which was 5.84 ppb. Standard deviations were 14.02 and 7.78 respectively (Tables 5 and 20). Even though serum PCB levels were higher among enrichment participants, the ranges are very narrow and the standard deviations are broad. It is, therefore, true that although differences were noted between these two groups, these differences are not likely to be biologically important.

One of the major points of interest regarding data collected on the enrichment sample was that, compared to the prevalence sample, the relationship of serum PCB level to age diminished greatly. The age confinement for enrichment participants may have masked this relationship. It is possible that the greater the exposure an individual may have had to PCBs, the weaker the association with age may be (Figure 12).

The difference in serum PCB levels for Portuguese/Cape Verdean and Non-Portuguese/Cape Verdean was also examined for participants of the enrichment study. The observed difference was also evident in this sample of higher risk individuals (Table 21). Although the sample size was much smaller in the enrichment study (n = 37; n = 73) vs. the prevalence study

(n = 415; n = 425), it is important to note that participants reporting their ethnicity as either Portuguese or Cape Verdean had a mean level of 17.1 ppb vs. 11.4 ppb for participants reporting their ethnicity as being other than Portuguese or Cape Verdean. However, variability of serum PCB levels in the Enrichment group was high (standard deviation ±12.5) and like the prevalence group, these differences may be explained by occupation and seafood consumption.

In any case, although some sub-groups within each of the study samples (i.e. prevalence and enrichment) exhibited higher mean and median levels than others, it should be kept in mind that the levels in both groups were generally low. Data available on how rapidly PCBs disappear from human serum is quite limited. Six persons from the present study were participants of 1981 investigation. The PCB serum levels for all six individuals dropped over the time that elapsed. The approximate decline in levels in this limited number of people was forty percent.

One of the issues of continuing concern in New Bedford has been whether exposure to contaminated seafood from local areas has resulted in elevated body burdens of PCBs among area residents and the percentage of the population of this area is affected. Over the last ten years a number of governmental agencies have conducted PCB monitoring of seafood. This sampling has consistently shown levels of PCBs well above the FDA action level of 2.0 ppm (formerly 5.0 ppm) in a number of species taken from these areas. This tolerance was adopted as the rationale for the harbor closure by the MDPH in 1979. Recent monitoring has indicated that elevated levels of PCBs in seafood have not appreciably decreased. Prior to the 1979 regulations these waters were popular as a recreational fishing ground as well as a lucrative commercial lobster fishery. Before results from

Phase I of the GNBHES were obtained, however, one could merely speculate as to the effectiveness of the prohibitions. It was clear from simple observation that fishing activities did not completely cease as a result of the ban. It was not possible, however, to estimate the decrease in terms of the number of people who formerly ate and no longer do, whether frequency of consumption has decreased among those who presently consume, and whether consumption has been high enough to be reflected in elevated body burdens. Because it is well recognized that there are some fish species which preferentially accumulate PCBs, information was sought to determine whether elevated serum PCB levels were associated with consumption of these.

Prevalence sample results have shown that serum PCB levels are low in general for the population of Greater New Bedford. It is also true that when questioned about seafood source only a small percentage of the greater New Bedford population is certain that they actually consumed fish from the closed areas. Even before the harbor closure this would seem to be the case. The majority of people in the New Bedford area seem to have had exposures to PCBs which have been similar to the general U.S. population. This is because the major route of exposure to PCBs today in the U.S. is from residues in commercial market fish. Because PCBs are stored in fatty tissue, body burdens gradually increase throughout life. This age trend has been shown in other studies (14) and is also seen in the Phase I Greater New Bedford Health Effects Study. Those who reported consumption of local seafood did have higher serum PCB levels in almost every age category (Figure 10) compared to those who did not consume. It should be stressed, however, that the range in levels is very small and most of those who consumed local species still had relatively low serum PCB levels. The

most likely explanation for this is that the frequency of consumption is not high. In other words, even though people report eating fish species from the contaminated areas, they do not eat large enough quantities of these species to markedly affect their overall body burden of PCB as reflected by serum PCB level. This infrequent consumption pattern was seen for lobster (Table 15), and is likely to be similar for other species. It was not possible to apply statistical tests for associations between serum PCB level and specific species since the cell numbers were small and the serum PCB level range was so narrow. This was the reason local seafood species were grouped for analyses.

In the enrichment population marked differences in seafood consumption patterns were noted. This, of course, was not surprising given the method of recruitment. This population clearly had a greater exposure to a variety of contaminated local seafood species (Tables 11 and 12), combined with a high general fish consumption. Some decreases in consumption were apparent as a result of fishery closures; however, nearly 62% still report continued or increased consumption of local species. As was seen with the prevalence sample, serum PCB levels increased with increasing frequency of consumption; however, serum PCB levels were still low in this group (Figure 11).

Because large numbers of persons were employed in the manufacture of electrical capacitors and other industries in which PCBs may have been used in New Bedford, information on industry of employment, selected types of manufacturing and exposure to specific materials was sought. Although some trends, (i.e., higher levels) among those employed in combined manufacturing industries were seen in quartile analyses, these were very weak. Observable trends in selected types of manufacturing and exposure to

specific materials were also weak and showed a lack of consistency between prevalence and enrichment responses. Low numbers of people in each data cell limit the ability to interpret these data.

The association of blood pressure and PCBs was examined in a study by Kreiss; diastolic blood pressure and PCB levels were significantly correlated.. However, the Kreiss et al study did not have a control group in its design; therefore, the high incidence of hypertension among the persons sampled confounded an explanation for the blood pressure and PCB association. In addition, there is a known relationship between age and blood pressure measurement; that is, blood pressure measurements, both systolic and diastolic, increase with age.

Other studies have demonstrated that serum PCB levels increase with age. It may be a spurious conclusion that blood pressure measurements (i.e. systolic and diastolic) are related to serum PCB levels since both tend to increase with age.

Other limitations to Kreiss et al.'s study include diagnosis of borderline or definite hypertension from single readings, unknown time of day when measurements were taken, and lack of control of the environment where the subjects' data were collected. In contrast, in the Greater New Bedford PCB Health Effects Study, blood pressure readings were taken at three times during the interview. (See Methods chapter for specific protocols.) The systolic and diastolic blood pressure readings for this study in the prevalence sample were significantly different from each other. This demonstrates the intermeasurement variability among blood pressure readings and the possible dependence of blood pressure on multiple external factors. While several multivariate techniques (e.g. multiple regression and log linear models) were applied to these data, no

significant model was found using age, body mass, systolic and diastolic blood pressure readings as independent variables, and serum PCB level as the dependent variable. The analyses by Kreiss et al. included multiple regression and log linear models. Accordingly, age, body mass and serum PCB levels were utilized as independent variables, and systolic or diastolic blood pressure readings as the dependent variable. Again, no significant model was found. Therefore, the relationships demonstrated in Kreiss et al.'s work were not found in the Greater New Bedford PCB Health Effects Study. Perhaps the lack of significant models was due to the low serum PCB levels found in the residents of the Greater New Bedford area and the presence of a normotensive sample. Kreiss et al.'s study included a higher number of borderline and hypertensive individuals. It was not reported whether these individuals were treated with anti-hypertensive medications; thus, the systolic and diastolic readings may have been distorted (36). The data in this study demonstrated no significant relationship between blood pressure measurements and serum PCB levels. As stated previously, both blood pressure measurements and serum PCB levels increased with age. However, further study in this area might include experimental designs with comparison groups stratified by age, etc. which deliberately control for extraneous variables such as pesticide exposure and renal function as well as a variety of health habits such as diet and exercise.

CHAPTER V

CONCLUSIONS

It is noteworthy that relatively few persons had elevated serum levels of PCB. This seems to indicate very little evidence of above normal exposure to PCBs among residents of the Greater New Bedford area. The findings suggest that the EPA ban of open-system use of PCBs in 1979 and the closure of New Bedford Harbor to fishing by MDPH in 1979, coupled with the considerable publicity over the hazards of eating locally-caught seafood have contributed to reductions of exposure via the food chain in recent years. It is also noteworthy that of those residents that were randomly selected (for determination of prevalence) less than 15% reported eating locally trapped lobster five or more times in their life and less than 2% report eating locally-caught eel; of those residents selected for participation for purposes of enrichment 63% reported eating locally-trapped lobster five or more times in their life and 25% reported eating locally-caught eel. These particular species were found to contain high levels of PCBs in the late 1970's (21), with concentrations in eels of up to 730 ppm and concentrations in lobster as high as 68 ppm and frequently greater than 10 ppm (2). Almost all individuals who were identified as being at the greatest risk of exposure via contaminated seafood intake, had relatively low serum PCB levels.

The risk of occupational exposure to PCBs has also greatly diminished since 1979. The serum PCB level analyses by quartile for occupational and material exposures for respondents of the enrichment study showed a higher frequency in the upper quartiles for those employed in electrical manufacturing. Exposure to certain types of materials are also seen with greater frequency in upper quartiles.

Observations among participants of the prevalence sample indicated higher frequencies in upper quartiles for those employed in manufacturing. Weak trends were also observed among males exposed to lubricants and rubber. Because there is little consistency between the two study groups and because data cells had very low frequencies, occupational exposures were not seen as an important contributor to elevated PCB body burdens in Greater New Bedford.

The conclusions to be drawn from the Greater New Bedford PCB prevalence investigation are: 1) that the prevalence of elevated serum PCB exposure among residents of Greater New Bedford is low; 2) even the residents at highest risk of PCB exposure from locally caught seafood consumption, for the most part, had levels within the typical range of the U.S. population; and 3) low and moderate serum levels of PCBs in this population do not appear to be associated with elevated blood pressure measurements. Enrichment sample analyses support the finding of the prevalence study with regard to decline in levels. It is possible that this group of individuals with "higher" PCB levels during the 85-86 investigation, may have had even greater levels if the investigation been conducted several years earlier, prior to the ban of open-system PCB use and fishing in and around the New Bedford harbor.

There are conflicting studies as to whether PCB exposure is related to blood pressure, independent of age and body mass. The Triana study showed a positive correlation after controlling for age, sex and Hollingshead index (2). The findings from that study differ from the New Bedford prevalence study in two important aspects:

(1) The levels of both blood pressure and serum PCB level were considerably higher in Triana than in New Bedford and,

(2) The rates of borderline and definite hypertension in Triana were

30% higher than those found on the National Health Survey, while those in New Bedford were within the normal U.S. range.

In addition, 21.4% of the Triana subjects had PCB serum levels greater than 30 ppb. It would appear that if there is a relationship between serum PCB level and blood pressure it is possible that there exists a threshold for the level of PCB that effects blood pressure. Any variation in blood pressure levels among participants of both the prevalence study and the enrichment study may be explained by age and body mass.

Because the literature on the half-life of PCBs in humans is sparse, it is not posssible to estimate how much higher serum PCB levels may have been several years ago. We conclude that low and moderate serum levels of PCBs do not appear to be associated with increased blood pressure readings. It should be noted that the residents of Triana were also heavily exposed to DDT and that serum PCB levels were correlated strongly with DDT serum levels, although DDT showed no effect in the regression model. Other studies have shown correlations between exposure to organochlorine pesticides in association with higher levels of blood pressure (6). Further studies should be attempted in populations with heavier PCB exposure which is not confounded by pesticide exposure to rule out the effects on blood pressure at higher exposure levels than were seen in the Greater New Bedford PCB Health Effects Study.

Although some of our findings support positive trends with past occupational and industrial exposures among those in the highest quartile of PCB level, the majority of those respondents still had levels within the typical U.S. range and it is likely that these levels will decrease over time as well. The GNBHES has generated a large data base that merits continued analysis.

RECOMMENDATIONS

(1) The current ban on fishing in and around the New Bedford harbor (i.e., the closure areas) should remain in effect until measurements in aquatic life decline to acceptable standards. Monitoring should be targeted on those species found to be consumed with the greatest frequency by the Greater New Bedford population.

(2) The Phase II study should not be conducted due to lack of a sufficient sample-size of 150 persons with PCB serum levels $\geq$ 30 ppb.

(3) Residents should refrain from obtaining and consuming recreationally caught seafood from the closure areas.

(4) Data collected for the GNBHES should be subjected to further analysis.

(5) Small scale follow-up studies should be designed by the MDPH to pursue certain areas of health research.

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